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Tuberous Sclerosis: A Family Study and Review of Its Osseous and Renal Manifestations

CHARLES A. GUNDERSEN, M.D.

ABSTRACT—The traditional concept of tuberous sclerosis is that of an inherited disease which manifests itself clinically by the classical triad of adenoma sebaceum, mental retardation, and seizures.

A family study is presented to indicate that this concept is a simplistic view applicable to only a small subgroup of afflicted patients and ignores the important internal manifestations of this disease.

The clinical, roentgenologic, and pathologic features of osseous and parenchymal involvement are reviewed to remind the physician that tuberous sclerosis is a systemic disease which may mimic other more common disorders.

Introduction

The traditional concept of tuberous sclerosis depicts this disorder as a clinical triad consisting of adenoma sebaceum, seizures, and mental retardation.

It has become increasingly evident that this concept applies only to a small number of patients and that it fails to consider the important internal manifestations of this disease.

This communication, which describes the clinical and laboratory findings in a twenty-two member family, supports the view that the classical triad is seldom present and that osseous and parenchymal involvement often dominate the clinical picture.

Patients and Methods

Personal interviews with complete history and physical were conducted on fifteen patients. The seven not interviewed were infants and small children whose medical histories were obtained from their parents and pediatricians.

An electroencephalogram (EEG) was obtained on twelve patients; complete bone survey on ten patients; intravenous pyelogram (IVP) with nephrotomograms on four patients; IQ testing (Wechler Adult Intelligence Scale) on four patients; and complete blood count (CBC), erythrocyte sedimentation rate (ESR), blood urea nitrogen (BUN), serum creatinine, calcium, phosphorus, and alkaline phosphatase on twelve patients.

Records pertaining to previous hospitalizations were obtained and reviewed on all patients.

The clinical and laboratory data on the nine patients with evidence of tuberous sclerosis are presented in tabular form. Complete case reports on two patients are presented.

Case Report I

A fifty-one year old woman was seen by her physician because of a complaint of epigastric pain. An upper gastrointestinal series was negative for intrinsic disease but an incidental finding of osteoblastic lesions involving the thoracolumbar spine was noted. She was admitted to a local hospital with a presumptive diagnosis of metastatic bone disease and a search for a primary tumor was initiated. The work-up which included an oral cholecystogram, barium enema, IVP, mammography, and pelvic examination with papanicolaou smear, failed to reveal an underlying tumor and she was referred to our hospital for further evaluation.

On physical examination, she had numerous yellow plaque-like lesions in a butterfly distribution over the face and subungual fibromas involving the left middle finger and fourth right toe. The remainder of the examination was normal. Complete blood count, ESR, urinalysis, serum creatinine, BUN, electrolytes, alkaline phosphatase, acid phosphatase, calcium, phosphorus, and protein electrophoresis were all normal.

The results of verbal, performance, and full scale IQ tests were 88,

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Reprint requests to: Department of Medicine, Hartford Hospital, 80 Seymour St., Hartford, CT 06115 (Dr. Gundersen).

96, and 91 respectively. A brain scan was normal and the EEG showed spike discharges in the right temporal region.

A chest x-ray was normal. A bone survey demonstrated numerous areas of mottled increased density involving the entire spine and pelvis (Figure 1). Areas of increased periosteal bone formation were seen in the metacarpals and metatarsals. Lucent lesions were present in several phalanges of the hands and feet. An IVP nephrotomography revealed bilateral irregular lucent lesions throughout the parenchyma, consistent with angiomyolipomas (Figure 2).

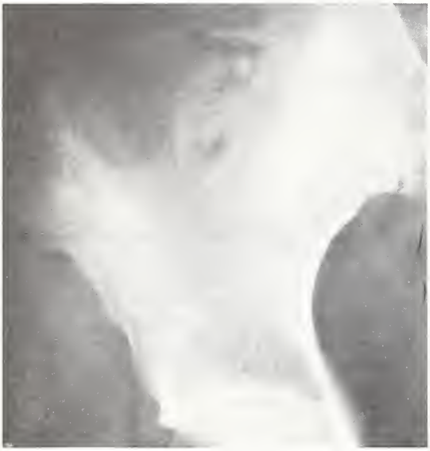


Figure 1
Coned view radiograph of right ileum showing large sclerotic area medially.

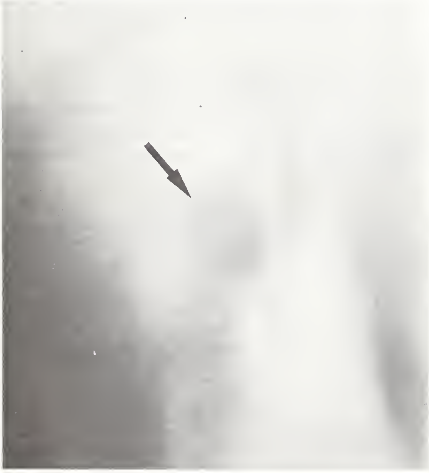


Figure 2
Nephrotomogram showing a large lucent filling defect due to hamartoma.

Case Report II

The twenty-eight year old daughter of Case I was admitted to a local hospital at age twenty-seven with the sudden onset of left flank pain, weakness, and diaphoresis.

Physical examination revealed an acutely ill woman with pallor and exquisite tenderness in the left flank. The hematocrit fell from 39 to 32 during the first six hours of her admission. She underwent an abdominal exploration for the presumptive diagnosis of a ruptured spleen. At operation, a large left retroperitoneal mass was found associated with massive bleeding. The mass and left kidney were removed.

The gross pathology revealed a large kidney with numerous yellowish grey nodules. The largest, measuring 4.8 x 3.8 centimeters, was embedded in the capsule and numerous smaller ones extensively involved the parenchyma. Continuous with the kidney was a 6.0 x 10.5 x 15.8 centimeter yellowish mass with a large tear along its surface with evidence of recent hemorrhage (Figure 3).

On microscopic examination, the intrarenal nodules and contiguous mass consisted almost entirely of adipose tissue with thin walled vascular channels and smooth muscle elements within its substance. The pathologic diagnosis was angiomyolipomas with hemorrhage (Figure 4).

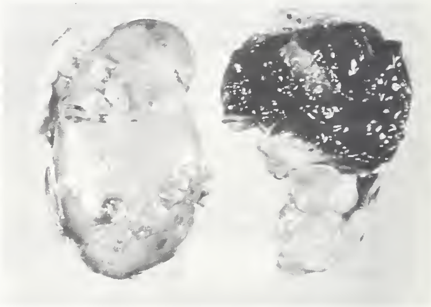


Figure 3
Bisected kidney showing multiple angiolipomas. The largest one is the site of recent hemorrhage.

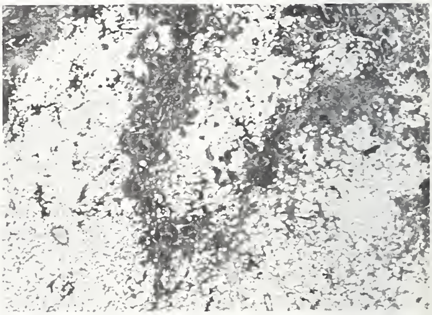


Figure 4
Histologic photomicrograph of resected angiomyolipoma showing a mixture of fat and thick-walled vessels with some smooth muscle component. (Hematoxylin and eosin; original magnification x 100).

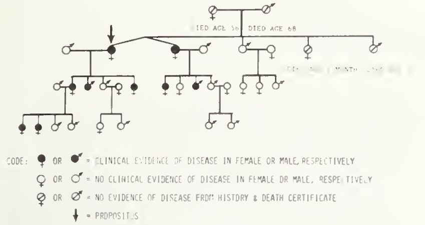
When seen by me, one year later, she was asymptomatic. The only positive physical findings were adenoma sebaceum of the face and a typical shagreen patch over the left flank.

Hematocrit, serum creatinine, calcium, phosphorus, alkaline phosphatase, and acid phosphatase were all normal. Brain scan and EEG were normal. Verbal IQ was 103, performance IQ was 108, and full scale IQ was 106.

Complete bone survey and chest x-ray were completely normal. A drip infusion intravenous pyelogram revealed compensatory hypertrophy of a solitary right kidney with numerous lucent areas of varying shapes, compatible with angiomyolipoma.

Results

Nine patients, four women, two men, and three children, had clinical evidence of tuberous sclerosis (Figure 5).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DIED AGE 68
CODE: ● OR ● = CLINICAL EVIDENCE OF DISEASE IN FEMALE OR MALE, RESPECTIVELY
♀ OR ♂ = NO CLINICAL EVIDENCE OF DISEASE IN FEMALE OR MALE, RESPECTIVELY
⊘ OR ⊘ = NO EVIDENCE OF DISEASE FROM HISTORY & DEATH CERTIFICATE
↓ = PROPOSITUS

Figure 5
Family pedigree.

Each of the nine had one or more of the external stigmata such as adenoma sebaceum, shagreen patches, and subungual fibromas. Fundoscopic examination was normal in all but one patient who demonstrated a retinal tumor.

All patients had normal average intelligence, as determined by the Wechler Adult Intelligence Scale in four, and scholastic and occupational performance in the remaining five.

Four patients gave a clinical history of seizures and had abnormal EEG's. Two had abnormal EEG's without a history of seizures. None of these patients had evidence of intracranial calcifications on the skull x-ray.

Three of the six patients who had radiographic bone surveys showed findings typical of tuberous sclerosis including osteoblastic changes, periosteal new bone formation in the metatarsals and metacarpals, and cystic lesions in the phalanges.

The chest x-ray was normal in the five patients on whom it was obtained.

Three of the four patients who had an IVP with nephrotomograms demonstrated multiple lucent lesions compatible with angiolipomas. The fourth had a suggestive but non-diagnostic study.

Renal function, as measured by BUN, serum creatinine, and urinalysis, was normal in all patients. All had normal serum calcium, phosphorus, and alkaline phosphatase.

Discussion

Tuberous sclerosis is a congenital disease transmitted as an autosomal dominant.[1]

The pathologic features were first described by Von Rechlinghausen in 1863, and further delineated by Bourneville in 1880. They consist essentially of multiple tumors and malformations involving the brain, skin, bone, and viscera. Histological examination reveals these tumors to be hamartomas.

This study supports the impression of others[2,3] that the traditional concept of tuberous sclerosis as a disease presenting with the clinical triad of adenoma sebaceum, seizures, and mental retardation is a constrictive one, applicable to only a minority of affected patients, and totally ignores the important internal manifestations of this disorder.

Both patients described, and seven additional family members with documented tuberous sclerosis, had average to slightly above average intelligence as measured by the Wechler Adult Intelligence Scale, school, and occupational performances. Only four of the nine had a documented seizure disorder. All displayed typical adenoma sebaceum, indicating that this may well be the most consistent finding in tuberous sclerosis.

The cases reported illustrate that tuberous sclerosis may extensively involve the bony skeleton and renal parenchyma, mimicking other disorders in the process.

The first case with generalized bone involvement illustrates how these lesions may be mistaken for metastatic disease leading the physicians to embark upon a fruitless search for a primary tumor.

Bone involvement in tuberous sclerosis is very common. The hands and feet were affected in 66 per cent of Holt and Dickerson's patients and 45 per cent of the Reed and Nickel's study group.[3,4] The most common radiographic findings consist of cystic changes in the phalanges and cortical thickening with periosteal new bone formation in the metatarsals and metacarpals. The cystic changes in the phalanges seem to be present from early childhood, whereas the cortical changes in the metatarsals and the metacarpals make their appearance at a later age.

The involvement of the spine or pelvis, or both occurs in about 40 per cent of patients.[5] The lesions are osteoblastic or sclerotic in appearance and range in size from a few millimeters to a few centimeters. Although the differential diagnosis includes osteoblastic metastases, Paget's disease, and osteopiokilosis, these entities can usually be distinguished from tuberous sclerosis by the experienced radiologist. In addition, a normal alkaline phosphatase as seen in all our patients indicates inactivity of the lesions in tuberous sclerosis as compared with those of Paget's and metastatic bone disease.

The skull x-ray usually shows abnormalities in about half of the patients.[6] These abnormalities may be

Table 1

SUMMARY OF FINDINGS IN 9 MEMBERS WITH CLINICAL EVIDENCE OF TUBEROUS SCLEROSIS

Patients	*Adenoma Sebaceum*	*Shagreen Patch*	*Subungual Fibroma*	*Seizures*	*Fundi*	*EEG*	*IQ*	*Bone Survey*	*Chest X-Ray*	*IVP*
MK, 51yo F	+	−	+	−	NL	AB	NL	AB	NL	AB
MW, 51yo F	+	−	+	−	NL	NL	NL	AB	NL	EA
PK, 28yo F	+	+	−	−	NL	NL	NL	NL	NL	AB
MW, 27 yo F	+	+	+	−	NL	AB	NL	AB	NL	AB
LK, 12yo F	+	+	−	+	ND	AB	NL	ND	ND	ND
GK, 25yo M	+	−	+	+	AB	AB	NL	NL	NL	ND
KK, 2½yo F	+	+	−	+	NL	AB	NL	NL	ND	ND
CK, 7yo F	+	−	−	+	NL	AB	NL	ND	ND	ND
PW, 27yo M	+	−	−	−	ND	ND	NL	ND	ND	ND

CODE: + = Present; − = Not Present; NL = Normal; AB = Abnormal
ND = Not Done; EA = Equivocal Abnormality

secondary to involvement of either the brain or bony calvarium. Intracranial calcifications may be noted which are contained in glial nodules located in the basal ganglia, cerebellum, or subcortical areas. Skull involvement consists of patchy areas of osteosclerosis similar to changes in the spine.

Case II, who was previously asymptomatic and undiagnosed, presented in a dramatic fashion. She became acutely ill and presented with signs and symptoms of an intra-abdominal catastrophe. She was found to have angiomyolipomas of the kidney.

According to Critchey and Earl,[7] angiomyolipomas are present in 89 per cent of patients with tuberous sclerosis. These tumors are usually multiple, bilateral, and vary greatly in size from a few millimeters to 15 centimeters in diameter. They are usually sharply demarcated from surrounding normal tissue, but not encapsulated. Sarcomatous change can occur in these tumors, but this is extremely rare.[8]

These tumors are usually asymptomatic, becoming clinically apparent in about 15 per cent of patients.[9] The most common clinical presentations include flank pain, palpable mass, hematuria, and massive intra-abdominal hemorrhage.[10] Renal failure may occur, but this is rare. Only five cases with this complication have been reported in the literature.[11]

The radiologic features of these tumors may be summarized as follows: Large tumors may be visualized on a plain film of the abdomen as a lucent mass overlying the renal shadow.[12] The IVP with tomography usually shows bilateral multiple lucent areas scattered throughout the renal parenchyma.[10 11] Stretching and distortion of the calyceal system may also be seen. Renal arteriography demonstrates hypervascularity with abnormal vessel distribution, vessel tortuosity, and puddling of contrast media in the nephrographic phase.[11] The findings are not specific for angiomyolipomas, since they may also be found in hypernephroma. However, the presence of out-pouchings from the interlobar and interlobular arteries is thought to be highly specific and diagnostic by some authors.[13]

The differential diagnosis of the radiologic findings in angiomyolipomas includes hypernephroma and polycystic kidney disease. Bilateral findings tend to exclude hypernephroma since bilateral renal involvement with hypernephroma is rare.[14] Polycystic disease can usually be differentiated by the arteriogram which shows the lesions to be relatively avascular in contrast to the hypervascularity seen with angiomyolipomas (Figure 6).

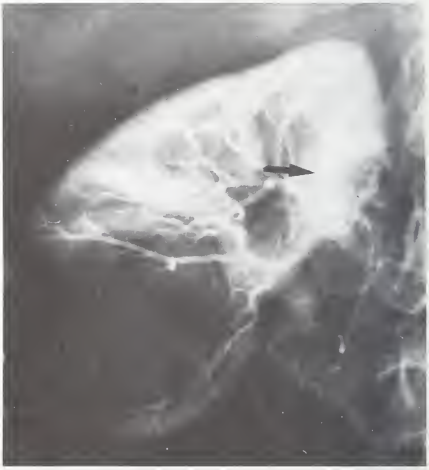

Figure 6

Frontal film from renal arteriogram showing a large avascular lesion (simple cyst) in lower pole with stretched and displaced vessels. Toward the upper pole is a neovascular lesion (arrow), showing puddling of contrast material, typical of hamartoma.

Knowledge of these various clinical presentations of tuberous sclerosis, and recognition of the typical external stigmata should enable the physician to arrive early at the correct diagnosis, and to avoid unnecessary diagnostic procedures, as in Case I.

Of equal importance is the fact that a diagnosis of tuberous sclerosis in a patient with overt disease makes it possible to identify affected family members who are asymptomatic and are unaware of their underlying disorder. This in turn provides the opportunity for genetic counseling and for proper interpretation of future abnormalities.

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Laboratory Induction of Colonic Neoplasms: A Review

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ABSTRACT—In the past, investigative activity involving colorectal carcinoma has been limited due to the lack of a laboratory model in which to study neoplastic phenomena in the colon. Although genetically inbred strains of rodents are known to develop a wide variety of spontaneously-occurring tumors, no strain develops a spontaneously occurring colonic carcinoma suitable for colonic research. In recent years a variety of agents have been discovered that are capable of inducing colonic neoplasms in rodents. A review of the chemical processes involved in tumor induction, modes of action, methods of administration and specificity of these agents is presented.

Carcinoma of the colon and rectum continues to be one of the major unresolved health care problems in the United States today. Numerous clinical studies appearing in the medical and surgical literature indicate the inadequacy of current treatment regimens, and that fresh insights into the disease are needed. Further investigative activity in the research laboratory concerning the etiology and biology of the primary and metastatic lesions are required. However, in the past investigative activity involving colorectal neoplasms has been restricted due to the lack of a non-human, laboratory counterpart to serve as a model in which to study the disease.

Genetically inbred strains of mice and rats are known to develop a wide variety of spontaneously

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occurring tumors depending upon the species and strain involved.[1] These spontaneously evolving tumors have served as reliable animal models for cancer research.[2] For example, seventy-eight percent of virgin females of AKR strain mice develop leukemia by eight and one-half months of age, and similarly, virgin C3H strain mice develop mammary tumors.[1] Unfortunately, a spontaneously occurring model of large bowel carcinoma does not exist in laboratory animals in a similar fashion.[3]

In 1963, Laquer reported that cycasin was capable of inducing tumors of similar pathology to human tumors in laboratory rodents.[4] Previously cholanthrene derivatives had been noted to induce neoplasms of the small bowel when added to the dietary intake of mice.[5] In general, the colon was not affected; however, 3-methylcholanthrene did produce some tumors.[5] Cholanthrene compounds are similar to bile salts in chemical structure, and it is possible that the carcinogenic properties of these compounds involve a direct effect upon the colonic mucosa after being metabolized and secreted in the bile.[5] Small numbers of colonic neoplasms are induced by substituted biphenyls, industrial dye derivatives which are known to be etiologic factors in the induction of human bladder tumors.[5] The etiology of colonic induction is not definite, but may also be related to biliary secretion of an active component into the intestinal lumen with subsequent passage into the colon with the fecal stream.[5]

Investigative utilization of cycasin is limited because it produces colonic neoplasms in only a small number of animals while simultaneously inducing tumors in a variety of other organs.[4] Furthermore, cycasin is obtained from the nuts of a tree indigenous to Guam and is thereby difficult to obtain. The carcinogenic potential of cycasin is thought to be related to an unstable water soluble glucoside of methylazoxymethanol, a cycasin metabolite.[6] Druckery produced tumors in large numbers of animals in the large and small intestine with dimethylhydrazine and noted its structural similarity to cycasin, and suggested a common intermediate metabolite as the actual carcinogenic agent.[5] Probably all compounds of this type are metabolized to methyldiazonium, a potent alkylating agent which spontaneously decomposes forming an activated free radical, carbonium ion, which methylates cellular nucleic acids resulting in genome alteration and eventual tumor formation.[5] Although abnormally methylated nucleic acids are observed in colonic epithelium of treated animals, they are also present in cells of other organs which do not develop tumors. The specificity of these agents for colonic neoplasm induction may be associated with the biliary secretion of active metabolites into the fecal stream as evidenced by the fact that diversion of either bile or the fecal stream away from the colon decreases tumor production.[7]

Narasawa demonstrated that N-methyl-N-nitroso-N-nitrosoquanidine, which causes upper gastrointestinal tumors in rats after oral administration, could induce colonic neoplasms upon intra-rectal administration.[8] No effect on colonic epithelium was noted with various other avenues of administration. Other alkylnitrosamides such as nitrosoureas also induce colonic tumors, the mechanism of which is thought to involve nucleic acid alteration and substitution.[6 9]

There are six major carcinogens capable of inducing colonic carcinomas in laboratory animals: dimethylhydrazine,[10 11] azoxymethane,[12 13] methylazoxymethanol,[14 15] methyl-N-nitrosourea,[9] N-nitroso-N-methylurethane[6] and methyl-N-nitro-N-guanidine.[8] All of these compounds induce tumors in large numbers of animals appropriately treated, although different avenues of administration are required.[6, 16] All of these compounds have a nitrogen grouping similar to that found in cycasin. Cell changes in the colonic mucosa are described in detail by Deschner, Ward, and Thurnherr.[11 12 13]

Although these agents reliably induce the growth of large bowel malignancies, they also induce the growth of tumors in organs in and outside the gastrointestinal tract.[6] Colon tumors predominate when they are administered by specific routes, none of which is oral.[6] The route of administration differs with each agent and the same agent administered by different avenues can produce tumors in different end organs.[5 17] In some compounds, the substitution of a chemical moiety alters the end organ affected, i.e., changing the methyl group to ethyl alters the end organ from either large or small bowel to liver and/or kidney.[18] Furthermore, each animal usually develops more than one tumor and up to forty bowel tumors in single animals have been reported.[11] The susceptibility does not seem to vary widely within members of any given strain.[10] Another major problem encountered by the investigator in the induction of large bowel carcinomas is the time-period required for induction to occur. The time-period required varies with the different agents, but in most cases is at least six months.[10] This is significant in that this period of time represents a large percentage of the life span of the average laboratory rodent.[1] All of these factors require refinement of the induction process in order to produce an animal model that has limited disease, and also require the transplantation of live tumor cells to younger animals for longer periods of study.

Transplantation of live tumor cells from animals in which tumor induction has been achieved into younger animals of the same strain or different strains has occurred.[13 16 19] Although the process is similar to that of any cellular transplantation technique, certain problems exist. Corbett and McCall[6 16] were able to transplant only certain specific tumors that they had induced.[6 16] However, once a tumor cell line was found to be transplantable, it remained transplantable through subsequent generations although several passages are required to regain malignant features.[16] The addition of isogeneic brain cells extract or irradiated tumor cells potentiates successful transplantation, the Revesz effect.[6] Using these techniques, only metastatic lesions have been produced, in that direct implantation of cells into colon was either not tried or not successful.[6 16] Metastatic lesions were either produced by subcutaneous injection or intravenous injection with growth in the lung.[6 16 20]

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As Others See Us—The Good Old Days

There are men and classes of men that stand above the common herd: the soldier, the sailor, and the shepherd not infrequently; the artist rarely; rarelier still, the clergyman; the physician almost as a rule. He is the flower (such as it is) of our civilization; and when that stage of man is done with, and only to be marvelled at in history, he will be thought to have shared as little as any in the defects of the period, and most notably exhibited the virtues of the race. Generosity he has, such as is possible to those who practise an art, never to those who drive a trade; discretion, tested by a hundred secrets; tact, tried in a thousand embarrassments; and what are more important, Heraclean cheerfulness and courage. So that he brings air and cheer into the sick room, and often enough, though not so often as he wishes, brings healing.

—Robert Louis Stevenson, Preface to *Underwoods.*

Season as a Factor in Variability of Blood-Lead Levels in Children

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ABSTRACT—Over 80% of the population of New Haven children from one through six years old had blood lead determinations during the period July 1974-February 1977. A major seasonal peak in lead levels occurred in the spring and summer months. The peak for values ranging from 30-39µg Pb/100 gm blood was in early May. Values 40-49 and 50-59µg peaked in early July and 60 + µg/100 gm values had a calculated peak in late July. Results demonstrated a large, population-based, pool of children with slightly to moderately elevated blood lead values in spring and summer months. This phenomenon may be explainable by regular seasonal interactions of diet, sunshine, vitamin D and availability of environmental lead.

Introduction

A large scale screening effort was carried out in New Haven, Connecticut from July 1974 through February 1977 to identify children at higher than normal risk of lead poisoning.[1] During these two and a half years, 8334 children, about 80% of the population of one to six year olds resident in the City, were examined one or more times. This program offered an opportunity to study the effects of season on blood lead levels in children.

All children who were screened had blood lead determinations although some also had free erythrocyte protoporphyrin (FEP) tests. Most of the more than 11,000 tests were made on micro samples (0.25 ml) of capillary blood, but approximately 900 macro samples (2-5 ml) of venous blood were examined. The examinations were made at every season of the year and the resultant data set was both large and representative of blood lead levels among the City's children over the entire period of the program. Therefore, after an evaluation of methods and results indicated that mean values for blood lead were probably reliable irrespective of micro or macro method, or season, or year of determination,[2] it was possible to analyze results for seasonal factors.

Seasonal variation in blood lead among children has been noted by several authors.[3 4 5] Suggested explanations for these effects have tried to relate them to factors known to affect lead intake, absorption, and toxicity. The factors include exposure, ingestion, diet, metabolism, temperature and occurrence of illness.

The most important of these factors is the actual ingestion of lead from environmental sources. It has been suggested that increases in blood-lead levels during the warm months may be due to increased ingestion of lead—containing materials such as outdoor paint, soil and suspended particulates.[6 7] In addition, parental supervision may be decreased during the summertime. No evidence has been offered either for or against this hypothesis, although Chisolm believes there is no reason to doubt that the affected children ingest lead throughout the year.[5]

For any given level of ingestion, absorption and toxicity vary with a number of concomitant dietary factors. In particular, calcium, phosphorus, iron and vitamin D are important. Most of the children at highest risk for increased lead ingestion tend to have diets low in calcium, iron and phosphorus,[8] as well as low in vitamin D.[6]

It has been established that increased vitamin D enhances the absorption of lead from the digestive tract

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of rats.[4,9] Although dietary levels of vitamin D remain fairly constant throughout the year, an increase in circulating vitamin D occurs during the Spring-Summer months due to increased exposure to solar radiation. Seasonal variation in circulating vitamin D occurs in human plasma, with the lowest levels occurring between November and March and the highest levels occurring between July and September.[10,11] The increase in vitamin D during the summer months has been implicated as a source of higher blood lead levels at this time.

Dietary deficiencies of iron, calcium, and phosphorus favor the absorption of lead from the intestine and increase its toxicity.[12-16] Low levels of vitamin D prevent the efficient utilization of dietary calcium. Because low levels of vitamin D tend to reduce uptake of calcium from the gut, it can be inferred that calcium levels are probably lowest in early spring. Decreased circulating calcium would be expected to facilitate the resorption of both calcium and lead that has been sequestered in bone. Evidence for decalcification of bone during mid-winter to early spring has been reported by Aaron, et al.[17] The release of lead previously incorporated in bone and its redistribution to soft tissues has been demonstrated in bone organ culture work.[18]

Hot summer weather, traditionally associated with more cases of childhood lead poisoning, may contribute to risk because it favors dehydration, a condition known to increase lead toxicity.[19] This effect may operate independently of the regular, seasonal vitamin D and calcium cycles even though they too are associated with climatic cycles.

An additional seasonally related influence on lead toxicity is acute infectious illness. This may occur in an individual at any time of the year and can precipitate symptoms and signs of lead poisoning in a child with chronic lead intake.[5] Within the whole population, however, there are fairly regular seasonal peaks of certain illnesses. For influenza and pneumonia, representative of respiratory infections in persons of all ages, there is a mid-February peak.[20] The peak occurrence of chicken pox, somewhat more representative of childhood diseases, is mid-March.[21]

Reports in the literature have been concerned only with the seasonal increase of acute toxic episodes of lead poisoning. In fact, 80% or more of acute toxic episodes occur during the summer months.[22] This report presents evidence that blood lead levels in the entire population of children reach a major peak in midsummer. This population-wide phenomenon appears to provide a substantial pool of children susceptible to clinical lead poisoning, even though very small numbers may actually develop symptoms. An understanding of this major peak is a prerequisite for better surveillance and intervention strategies. Analysis of other, smaller seasonal variations in blood lead is given in a separate report.

Methods

There are several statistical methods for testing for seasonality. The Edwards test[24] and its variations are based on the model of twelve weights distributed around a circle and the calculation of the center of gravity for a particular distribution of weights. The twelve weights are the number (n_i) of cases occurring for each month. The square root of n_i is used in order to modify the effect of an unusual increase or decrease which may occur in one month but which is not repeated in corresponding months in other years. If we let $(\bar{x},\bar{y})$ by the coordinates of the observed center of gravity and $E(\bar{x},\bar{y}) = (0,0)$ be the coordinates of the expected center of gravity, we can compute a test statistic X^2. In addition, we can calculate the angle θ, to determine where the peak incidence of cases occurs.

Table 1

NUMBERS AND PROPORTIONS OF BLOOD-LEAD VALUES WITHIN 5 LEVELS BY MONTH OF INITIAL TEST

Month	*# Children < 30 ug% (p)*	*30-39 ug% (p)*	*40-49 ug% (p)*	*50-59 ug% (p)*	*60 + ug% (p)*	*Total #* Screened*
January	366 (.662)	139 (.251)	42 (.076)	6 (.011)	0 (.000)	553
February	329 (.575)	191 (.334)	42 (.073)	10 (.018)	0 (.000)	572
March	258 (.499)	207 (.400)	46 (.089)	4 (.008)	2 (.004)	517
April	377 (.640)	173 (.294)	29 (.049)	9 (.015)	1 (.002)	589
May	298 (.641)	130 (.280)	25 (.054)	10 (.022)	2 (.004)	465
June	262 (.456)	229 (.398)	57 (.099)	21 (.037)	6 (.010)	575
July	471 (.432)	402 (.369)	146 (.134)	49 (.045)	23 (.021)	1091
August	495 (.461)	385 (.359)	137 (.128)	42 (.039)	14 (.013)	1073
September	218 (.552)	117 (.296)	32 (.081)	17 (.043)	11 (.028)	395
October	674 (.730)	180 (.195)	55 (.060)	11 (.012)	3 (.003)	923
November	676 (.701)	222 (.230)	49 (.051)	16 (.017)	2 (.002)	965
December	346 (.565)	204 (.333)	53 (.087)	4 (.007)	5 (.008)	612
						8330

* Note: 4 children were eliminated from total due to missing data

Table 2
SEASONAL VARIATION IN CHILDREN'S BLOOD-LEAD LEVELS

	30-39 µg%	*40-49 µg%*	*50-59 µg%*	*60 + µg%*
$\bar{x}$	−0.0607	−0.0990	−0.2276	−0.3901
$\bar{y}$	−0.0155	−0.0593	−0.0718	−0.1762
$E(\bar{x})$	−0.0331	−0.0331	−0.0331	−0.0331
$E(\bar{y})$	−0.0534	−0.0534	−0.0534	−0.0534
var ($\bar{x}$)	0.00005	0.00018	0.00065	0.0019
var ($\bar{y}$)	0.00005	0.00018	0.00065	0.0019
X^2 seasonal trend	43.9634	24.3201	58.7213	75.0152
Sig. level	0.0000	0.0000	0.0000	0.0000
θ	126.0631	185.1143	185.4040	198.9832
month	early May	early July	early July	late July

The beginning and end point for calculating θ is the new year (0°, 360° at January 1st, December 31st). April 1st is 90°, July 1st, 180° and October 1st, 270°.

Results

Table 1 presents the numbers and proportions within each of the twelve months of the year of blood-lead test results grouped by five levels, in µgPb/100 ml of blood, namely < 30; 30-39; 40-49; 50-59; 60+. These categories correspond to estimates of clinical significance. Within each month, the largest proportion of subjects falls in the assumed normal category below 30µg, with decreasing proportions of the screenees falling into successively higher blood lead categories. Within a given category, one can compare the variation in proportion by month and observe that proportions in the three higher value categories (above 40µg) tend to be lowest in the winter months and highest in the mid to late summer periods.

Table 2 shows the results of the Edwards test on data from Table 1.* The peak incidence of blood lead values in the 30-39 µg range occurred in early May while the 40-49 µg and 50-59 µg peaks were in early July and the 60+ µg peak was in late July.

Discussion

These results demonstrate a significant summer peak in children's blood-lead levels. The beginning of this peak, however, occurs in spring when the incidence of blood-leads in the 30-39 µg% range is at its peak. The build-up continues through the summer, with the peaks for higher values occurring progressively later. By defining the level indicative of undue absorption to be 30 µg%,[4] the date of onset of increased incidence has been shifted from June[7,24] to May.

This major seasonal peak could be explained by cyclic trends in circulating vitamin D superimposed on low levels of dietary calcium and fairly constant significant levels of lead intake. Decreased circulating calcium in early spring may operate to promote mobilization of sequestered bone lead. During late spring and early summer months, increased vitamin D resulting from increased solar radiation could cause increased absorption of ingested lead from the intestinal tract. Toxicity at this time would also be increased by dehydration due to increased ambient temperatures. Thus, the principal peak in increased blood lead levels occurs between May-August.

Conclusions

Examination of the seasonal variation in blood lead levels in a sample of over 80% of New Haven children aged one through six over a two and a half year period showed a summer seasonal rise whose start could be traced back to early May. This is considerably earlier in the year than has been observed in studies based on children with symptomatic lead poisoning. We have hypothesized a mechanism which is based on regular external and internal seasonal events. We believe that individual factors, either environmental or behavioral, leading to acute lead poisoning are superimposed on a few children within the enlarged summer pool of susceptibles. The regularly recurring events include normal seasonal changes in vitamin D in plasma, superimposed on low dietary intake of calcium, and constant intake of lead, and temperature variations. It must be remembered that in order for lead to be mobilized from bone it must first have entered the child's system. Although we may have identified contributory factors in the occurrence of increased blood lead levels, the ingestion of lead-containing materials remains as the primary problem.

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Laboratory Recognition of Campylobacter Enteritis

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ABSTRACT—*Campylobacter fetus* subsp. *jejuni* was isolated from 14 out of 434 unselected patients with diarrhea. The age of patients ranged from 15 months to 72 years. Skirrow's selective medium was found to be an effective medium for the primary isolation of the organism. A simple procedure which is easily done in the physicians' office is Wright's stain of the fecal smear. The observation of vibrio-like organisms and polymorphonuclear leukocytes strongly suggests the presence of *C. fetus.* In vitro antibiotic susceptibility testings indicate that both erythromycin and gentamicin are highly effective drugs.

Campylobacter fetus, formerly known as *Vibrio fetus,* is a small, microaerophilic, Gram-negative curved rod. The new generic term *Campylobacter* meaning "curved rods" in Greek was proposed by Sebald and Véron[1] in 1963 because the microaerophilic vibrios were different biochemically, serologically and genetically from the classic cholera and halophilic vibrios.

Campylobacter fetus is well known in veterinary medicine as a cause of infectious infertility and abor-

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tion in cattle and sheep. Three subspecies have been identified: *fetus, intestinalis* and *jejuni.* In humans, *C. fetus* subsp. *fetus* is of little clinical importance. *C. fetus* subsp. *intestinalis* often causes opportunistic infections in elderly patients with severe underlying diseases. On the other hand, *C. fetus* subsp. *jejuni* is capable of causing gastroenteritis in otherwise healthy individuals.[2,3,4,5]

Campylobacter gastroenteritis had been diagnosed only occasionally by positive blood cultures[6,7] until Butzler *et al* in 1973[8] and Skirrow in 1977[9] developed special selective isolation procedures. Using their methods, *C. fetus* subsp. *jejuni* was isolated in 4 to 30% of children and adults with diarrhea.[10,11,12] Thus it is clear that *C. fetus* subsp. *jejuni* is a common cause of gastroenteritis.

In this paper, we will report both the frequency of Campylobacter enteritis diagnosed at Mount Sinai Hospital and the laboratory experience with the organism.

Materials and Methods

All stool specimens and rectal swabs received in the diagnostic laboratory were routinely cultured for *Salmonella, Shigella, Yersinia* and *C. fetus* subsp. *jejuni.* No attempt was made to isolate enteropathogenic *Escherichia coli* or to search for virus. The procedure of cold enrichment for the isolation of Yersinia[13] was included during the second 6-month study.

The selective medium used for the recovery of *C. fetus* subsp. *jejuni* consisted of Columbia agar base, 7% lysed sheep blood cells, polymixin (2.5 I.U./ml.) vancomycin (10 µg/ml) and trimethoprim (5 mg/1). This mixture of antibiotic supplements was purchased from Oxoid, England. Plates were incubated at 42°C for 48 hours in an atmosphere consisting of 5% oxygen, 10% carbon dioxide and 85% nitrogen. This mixture was achieved by evacuating two-thirds (gauge reading of 26 inch) of the air in a Torbal anaerobic jar without a catalyst. The evacuated air was replaced with a mixture of 10% carbon dioxide and 85% nitrogen. Plates were examined at the end of 24 hr. and 48 hr. incubation. Colonies which were pinkish, mucoid and flat were further studied by both phase contrast microscopy and Gram stain (using 1:5 dilution of safranin as the counterstain). Identification was based on the typical morphology and characteristic darting motility, positive catalase and oxidase reactions and growth at 37°, 42°C, but not at 25°.[14]

All loose, watery or blood-stained stool specimens were smeared and examined for the presence of leukocytes by Wright's stain.

Results

C. fetus subsp. *jejuni* was isolated from stools of 14 patients with symptoms of gastroenteritis, during a 12-month period from October 1, 1978 to September 30, 1979. No *C. fetus* subsp. *jejuni* was isolated from stools of 128 healthy hospital employees. These patients included 10 hospital admissions, 2 outpatients and 2 household contacts. Among patients with gastroenteritis, *C. fetus* is cultured less frequent (3.2%) than Salmonella (4.3%), and more often than Shigella (1.1%) or Yersinia (0%) (Table 1). There is no indication of a seasonal variation of this infection.

Table 1
FREQUENCY OF ENTERIC PATHOGENS IN STOOLS AT MSH
(OCTOBER, 1978 TO SEPTEMBER, 1979)

	Patients			*Controls*
	< 21 yrs. (183)	*> 21 yrs. (251)*	*%*	*(128)*
Salmonella	12	7	4.3	0
Campylobacter	4	10	3.2	0
Shigella	1	4	1.1	0
Yersinia	0	0	0	0

Thayer-Martin medium (TM), a selective medium for the isolation of pathogenic Neisseria, has been suggested as an alternative plate for the cultivation of *C. fetus* subsp. *jejuni.* Thayer Martin medium has ingredients similar to but not identical with Skirrow's medium. We tested the potential usefulness of TM by comparing the plating efficiencies of these two media using our clinical isolates. The plating efficiencies ranged from 0 to 0.5% on TM as compared to Skirrow's medium. Colony sizes were generally smaller on TM. We conclude that TM is not as effective as Skirrow's medium when used for primary isolation of *C. fetus* subsp. *jejuni.*

Stool specimens from nine patients were watery and blood-stained, suggesting that specimens were obtained in the acute phase of their illness. Fecal smears stained with Wright's solution revealed the presence of polymorphonuclear leukocytes varying from 1 to 10 per fields. On the same smear, curved organisms could be easily recognized. They had a tendency to concentrate at the edge of the smears. (Figure 1).

Figure 1
Wright stain of a fecal smear showing Vibro-form organisms.

We tested 13 clinical isolates for their susceptibilities to 5 antibiotics using the agar dilution method of Vanhoof et al.[16] The Minimum Inhibitory Concentration (MIC) of ampicillin ranged from 2.9 µg/ml to 30.5 µg/ml or greater. Likewise, tetracycline showed variable results with MIC ranged between 0.72 ug/ml to 30.5 µg/ml. Erythromycin, gentamicin and chloramphenicol were very active against all isolates with MICs of 0.72, 0.18 and 3.8 µg/ml, respectively.

Eight patients were treated with erythromycin and one with gentamicin. These nine patients responded well with no clinical relapse. The remaining five cases recovered without antibiotics.

Discussion

Our findings confirm the earlier reports that *C. fetus* subsp. *jejuni* is a common causative agent of enteritis with a frequency only second to that of *Salmonella* sp. at Mount Sinai Hospital. *C. fetus* subsp. *jejuni* appears to affect patients of all ages. We have observed that adults manifest a more severe clinical course with *C. fetus* than with Salmonella sp. and thus may require hospitalization.

Campylobacter bacterium stains poorly with the Gram stain, but stains better if the counterstain solution is diluted 1:5. However, the organisms are easily recognized with Wright's stain. Karmali et al[10] recommended direct examination of the fecal specimen with phase-contrast microscopy as a sensitive screening procedure for *C. fetus.* In our hands, the Wright's stain of a fixed fecal smear is much easier to read than the wet-mount preparation, because Campylobacter bacterium is very small and easily obscured by other motile organisms in the fecal flora. The efficacy of the Wright's stain of fecal smears as a screening procedure deserves careful evaluation. The simplicity of the procedure makes it a promising diagnostic test which can be easily performed in a physician's office.

There are several methods for obtaining the proper atmosphere for isolation. In addition to the method used in this report, one can use a GasPak anaerobic generator in a jar without a catalyst or the use of the Fortner principle.[17] The latter method is probably the most practical for laboratories that process a small number of specimens. Basically, the method involves inoculating half of a plate with the specimen and the other half with a resistant stain of *Proteus rettegeri.* The plate is then wrapped in an air tight plastic bag and incubated at 42°C. The growth of the *P. rettegeri* provides the reduced oxygen atmosphere for isolation.

The clinical manifestations of Campylobacter enteritis cannot be readily distinguished from those caused by other enteric pathogens. The diagnosis depends on laboratory isolation of the organism. In view of the high incidence of Campylobacter enteritis that has been observed by us and others, it is recommended that this organism should be added to the list of enteric pathogens routinely recognized in the laboratory.

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Resistant Mycobacterium Tuberculosis: Report of a Family in Connecticut

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Continuing surveys of Mycobacterium tuberculosis, both in the United States and Canada,[1-5] have demonstrated a stable level of resistance to the primary chemotherapeutic agents. The two countries have noted an increased incidence of resistant M tuberculosis in immigrants from Asia and in the Hispanic population.[4,5] These studies have focused on the first line drugs including isoniazid, streptomycin, and para-aminosalicylic acid. Less than two percent of organisms tested were resistant to rifampin or ethambutol. Simultaneous resistance to two first-line drugs was distinctly unusual.[2-4] We report a Greek immigrant family where the father and daughter had active pulmonary tuberculosis, resistant to both isoniazid and rifampin.

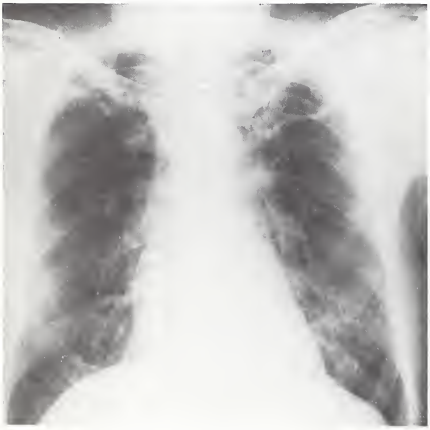

Figure 1

Case Reports

Case 1: A 48-year-old Greek male came to the United States in 1974. At that time, the chest radiograph demonstrated a left upper lobe cavity (Figure 1). Sputum cultures were negative for mycobacteria and isoniazid was recommended. The patient took an unknown quantity of isoniazid irregularly for one or two months, discontinued it, and was lost to follow-up.

In December, 1976, he was admitted to the Yale-New Haven Hospital where a gastric ulcer was documented and treated. The chest radiograph demonstrated an increase in size of the left upper lobe cavity, (Figure 2). The sputum smear was positive for acid-fast bacilli, and isoniazid and ethambutol were begun. The prior history of intermittent isoniazid therapy was not obtained at that time. The patient was discharged home and followed as an out-patient.

Sputum smears rapidly became negative, and only four to six colonies of M tuberculosis could be cultured. The sensitivities are seen in Table 1. The patient responded clinically and radiographically to therapy despite the in-vitro resistance to isoniazid and rifampin.

After ten months of therapy, the radiograph demonstrated cavity closure and was stable; sputum smears were negative. However, the sputum culture remained positive for M tuberculosis. Repeat sensitivities in December, 1977, (Table 1) again demonstrated isoniazid resistance; the rifampin resistance was also confirmed. Additional confirmation of the sensitivities was provided by the Special Reference Laboratory at the West Haven Veterans Hospital. Therapy was changed to include the following: streptomycin, pyrazinamide, ethionamide, and isoniazid. The patient tolerated the regimen well, and his smears and cultures became negative. There was no further change in his radiograph.

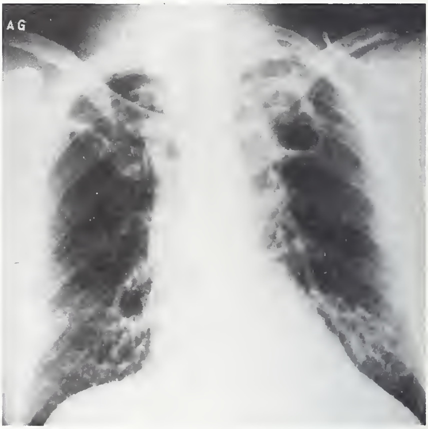

Figure 2

Case 2: This, the 16-year-old daughter of Case 1, was referred to the

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Table 1
MYCOBACTERIUM TUBERCULOSIS DRUG SUSCEPTIBILITY

Lab.	*Yale-New Haven Hospital*	*Yale-New Haven Hospital*	*Special Reference Lab for Tuberculosis (West Haven VAH)*
Date of Culture	Feb. 1977	Dec. 1977	Dec. 1977
	% Resistant Colonies		*Growth*
Isoniazid			
1.2 mg/ml.	33	19	3+
5	2	0	2+
Rifampin			
1 mg/ml.	86	100	3+
5	81	95	3+
Streptomycin			
2 mg/ml.	80	27	0
10	0	0	0

clinic as a household contact. Her initial evaluation included a normal physical examination and chest radiograph. An intermediate purified protein derivative skin test (PPD) was positive and she was begun on INH chemoprophylaxis. While she was being followed, it became evident on serial chest radiographs that there was an enlarging parenchymal mass in the right upper lung zone. This was confirmed by chest laminograms. Although the sputum smears and cultures remained negative for acid-fast bacilli, a presumptive diagnosis of active pulmonary tuberculosis, resistant to isoniazid and rifampin, was made. Treatment included isoniazid, intramuscular streptomycin, ethionamide, and ethambutol.

Subsequently, the right upper lung zone lesion decreased in size. The patient tolerated the regimen well and all sputum smears and cultures remained negative.

Discussion

This report illustrates several important aspects of the treatment of tuberculosis. It is well-recognized that the irregular use of chemotherapy predisposes to the development of resistant organisms. As the possibility exists that the index case initially was sensitive to isoniazid, one cannot exclude the possibility that he developed his isoniazid resistance in that period of time during which he took the drug haphazardly. There was no history of exposure to rifampin either in Greece or the United States.

When the patient was first referred to the clinic for continuing out-patient care, his family was evaluated. In addition to Case 2, the patient's wife and three other children were carefully followed over several years. In none of these was active tuberculosis infection detected. The problem of prophylasis with INH in the foreign born has been discussed by the Ad Hoc Committee of the American Thoracic Society.[6] Their recommendations were: either to observe the contact and treat with two or more drugs to which the organism is known to be susceptible if active disease should become manifest; or to give prophylactic treatment with rifampin. In the present report the latter case might have been, unfortunately, as unsuccessful as prophylaxis with isoniazid had been. Our experience would suggest a preference for the former option of close observation of the contact.

It has been suggested that while patients are receiving isoniazid chemoprophylaxis, chest radiographs are not required.[7] We recommend, based on our experience with this family, that when contact of patients with active, resistant tuberculosis are being followed, chest radiographs play an important role in the management of the patient. The sputum smears and culture may be negative while the chest radiograph begins to develop significant changes.

In view of the increasing incidence of resistant tuberculosis abroad, we recommend that therapy should be initiated with three first-line drugs in those cases where the infection may have been acquired outside of the United States. We decided to continue the isoniazid, as part of the chemotherapeutic regimen, despite the in-vitro resistance demonstrated. Our reasons were (1) isoniazid-resistant strains of M tuberculosis may be less virulent than isoniazid-sensitive strains;[8] and (2) in-vitro resistance may not correlate with the in-vivo response.[9] The latter observation is supported in the primary case, in part by the significant clinical and radiographic improvement in the first ten months of therapy.

In conclusion, we wish to emphasize the need for obtaining a complete drug history; and in patients who have immigrated to the United States, obtaining drug sensitivities when chemotherapy is begun rather than at the time of treatment failure if it should occur. In addition, careful monitoring of the close contacts of such cases will be necessary to prevent spread of resistant organisms throughout the community.

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CT and Ultrasound: Clinical Applications in Search of an Abdominal Abscess

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Introduction

Ultrasound and Computed Tomography (CT) are vastly different imaging modalities most similar in their time frame of development.

As with conventional radiography, CT images rely upon differences in tissue atomic number and density. The computed enhanced and digitalized display allows smaller differences of attenuation to be recognized than ever imaginable simply using film covered with photographic emulsion.

Ultrasonic images are dependent factors only in part understood. Tissue elasticity and inhomogeneity seem to account for most reflections of the sound beam. These "echoes" are digitalized in modern units with enhancement given to the low energy reflections so that "grey scale" images demonstrate, for example, the detailed dimensions of even normal pancreatic and bile ductules.

Since the attenuation differences of tumor vs. normal tissue are usually not great enough for recognition even by CT scanning, current units rely mainly upon deformed organ boundaries for diagnosis. Because tumorous changes radically affect ultrasonic characteristics, small and even non-deforming lesions may be imaged.

Little additional training of registered X-ray technicians is needed for running even the most modern CT scanners. Sonographic technicians—"Sonographers"—in many ways must be physician assistants with a complete knowledge of normal abdominal anatomy, and the ability and judgment to recognize and record abnormalities when found. Training of *at least* one additional year is needed to achieve this high level of expertise.

The reading of CT scans is comparatively easier than ultrasound, as CT images are much like conventional and more familiar radiographs. Distortions of body symmetry are frequently readily apparent on CT's full body sections. Ultrasound is more open to misinterpretation because of the versatile planes of imaging and frequent lack of recognizable anatomic landmarks. The most valid interpretation often belongs to the physician in attendance during the performance of the ultrasound examination. CT does not necessarily have this limitation.

Because of this versatility, however, ultrasound promotes all degrees of oblique views, decubitus, supine, prone and even standing patient positions. Only by image computer "reconstruction" can CT approach this variability of display.

The hazards of electromagnetic radiation plus the physical boundaries of the machine's hull inhibit physical examination during a CT test. Of all imaging

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modalities, ultrasound is best able to simultaneously match areas of tenderness or palpable masses with imaged anatomy. Ultrasound enhances the physical examination.

In addition, the pregnant and at times the very young need special consideration in terms of radiation exposure. Ultrasound has not yet proven to be hazardous.

Patients with abundant fat planes have organs with better defined boundaries on CT evaluation. These same patients, however, may be poor candidates for ultrasound study, as fat tends to reflect and scatter the sound beam. Penetration and resolution are thereby limited. Likewise air-filled bowel loops often prohibit examination of the midabdomen for ultrasound. CT is especially well-suited for these regions. Thin patients without adequate fat planes for CT imaging make ideal candidates for ultrasound. In general if one can palpate a lesion, ultrasound will be best able to document its nature.

CT evaluation is most successful when bowel is spacified by oral contrast, vessels and kidneys by intravenous injections, and peristalsis halted by glucagen. Short periods of breath-holding are needed for maximal resolution. Patients unable to be moved into the machine's hull, of course, are not able to undergo this examination.

Comparing the two modalities is inevitable but perhaps not a totally worthwhile exercise, as stress in usage generated by parochial interests, funding, expertise and patient population is as variable as is every hospital. A wide range of "accuracy" can be found in reports for each modality.

A more crystalized understanding of CT's and ultrasound's potential use and reliability in diagnosis will be possible only after continued individual experience particularly when limited to one's own locale of practice.

Abdominal Abscesses

The accuracy of identifying abdominal abscesses vary with institutions and no doubt this is a reflection of local expertise and enthusiasm as much as the inherent abilities of each test. Some institutions report nearly routine use of CT scanning for abdominal abscess evaluations, and only occasional application of ultrasound; these roles are reversed elsewhere. Accuracy figures vary accordingly.

The Mallinckrodt Institute reports correctly identifying 6 of 9 patients with proven abdominal abscess in a series of 45 cases.[1] Twenty of twenty-two proven abscesses were found by CT in a review in the Cleveland Clinic.[2] A total of only four ultrasound examinations were done at these institutions.

In comparison, abdominal abscesses are quite routinely evaluated by ultrasound at Yale-New Haven Hospital, where a sensitivity of 93% and a specificity of 98%'were reported by Taylor in a series of 220 patients.[3] This level of accuracy was confirmed by Korobkin,[4] who found ultrasound to be 96% accurate.

Less enthusiastic results emanate from the Surgical Department of Arizona State documenting an accuracy of 75% for ultrasound, and 67% for CT.[5] This report perhaps more correctly reflects the mean experiences as well as the expertise nationwide.

It should be recalled that the dependent portions of the abdominal cavity are the most frequent sites for abscess collections. Fortunately, the subhepatic subphrenic and pouch of Douglas and Morison are areas especially well-suited for ultrasound study as the liver, spleen and urine filled bladder provide excellent acoustic windows.

Ultrasound allows simultaneous palpation and imaging without the dangers of radiation. In searching for a fever source, it is quite helpful to correlate areas tender or palpably full with anatomic correlates. It thereby seems reasonable to include the ultrasound examination in the initial battery of tests,[4 10] as it approaches most exactly an extension of the physical examination—the most important "test" in the evaluation of patients acutely ill.

Ultrasound should be done prior to any barium study, but after plain film studies of the abdomen. A urine-filled bladder is needed to provide an "acoustic window" for viewing pelvic anatomy.

Abscesses typically have a complex ultrasonic appearance disrupting normal tissue architecture. (Figure 1). Lower level echoes represent pus and at times debris is noted as medium-ranged densities often layering and moving with change in patient position. High level echoes surrounding an abscess represent the collagen, fibrous wall packeting inflammatory foci. A gas-producing abscess will be recognized by air's typical echogenic and beam scattering qualities.[6]

The very obese suspected of an upper or midabdominal abscess, or the post-surgical with multiple drain and wound sites—not allowing complete physical examination or transducer contact—are primary candidates for CT evaluation. (Figure 2).

Although reports of successful imaging of retroperitoneal abscesses by ultrasound,[7] CT is probably better equipped for these cases, as deep fat and muscle anatomy is exquisitely imaged by this modality.

Abscesses typically produce low attentuation masses disturbing normal anatomic boundaries. Bowel opacification with an oral contrast agent is especially important in identifying an intra-abdominal abscess as a collection of unopacified bowel loops may mimick its appearance.

The full extent of needed drainage may be better defined by CT as its scope of evaluation more fully includes the deep retroperitoneal structures.

Subphrenic regions, however, may be relative "blind areas" for study. The transverse sections limit resolution of diaphragm and adjacent viscera while heart motion further degrades detail in this region.

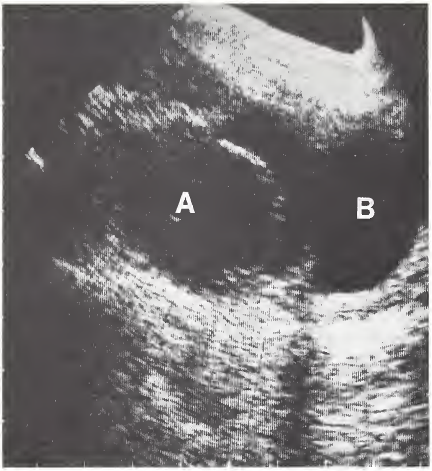

Figure 1
A pelvic abscess (A) having a typically complex ultrasonic appearance is found in a dependent portion of the pelvis, and compresses bladder (B), on this longitudinal scan.

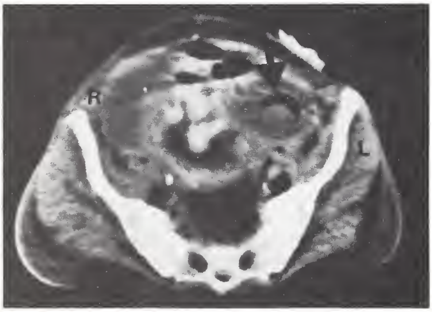

Figure 2
An air containing mass (arrow) demonstrated on CT section through upper pelvic region proved to be an abscess, Right = R, Left = L.

While Korobkin has reported an overall equal accuracy in detecting abdominal abscesses, both CT and ultrasound diagnoses were found benefited by correlation with gallium scanning.[4] Taylor has supported this finding,[8] again noting the enhanced specificity of this combined approach. It may be helpful to reorder, therefore, an ultrasonic or CT study when initial examination is found in conflict with the less specific but possibly more sensitive gallium scans, within the proper clinical setting. The diagnostic limitations, strengths and protocols of gallium scanning are beyond the scope of this review but have been more than adequately reported.[11 12]

For both CT and ultrasound, a defined complex mass may represent something other than abscess. Tumor, hematoma, bowel adhesions, etc., may present with a wide range of ultrasonic,[9] and CT findings,[2 4] at times mimicking abscess. Optimal examination would connect clinical and laboratory clues with imaged anatomy. The clinical staff can promote this by providing such information when available to the consulting ultrasonologist/radiologist.

Conclusion

Both ultrasound and CT have been shown to be highly accurate means of diagnosing abdominal abscesses. The degree of accuracy will depend in part upon local expertise, especially for the more operator dependent ultrasonic examination.

Ultrasound best serves as the initial study, after plain film radiographs, and especially when acute findings and symptoms lead to a specified area of interest. While CT is better suited for the obese and those strongly suspected of a retroperitoneal process, required patient cooperation and the hazards of radiation may at times limit its application.

Both studies are benefited by a complete clinical history, correlated physical examination and direction by gallium studies.

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MEDICAL ONCOLOGY AT YALE

Acute Adult Myelocytic Leukemia: Dilemmas in Its Management

THOMAS P. DUFFY, M.D.

ABSTRACT—Successful induction remission rates of close to 80% are now possible in adult acute myelocytic leukemia, a disease which previously was characterized by an almost universally rapid and lethal outcome. However, successful induction has not led to cure of the disease; the median survival period is still only 19-24 months. Innovative but unproven treatment modalities including more aggressive maintenance regimens, immunotherapy and bone marrow transplantation are now available in pursuit of cure of AML. Dilemmas regarding the choices and use of therapies have been created. The unproven effectiveness of the novel treatment methods is associated with a trade-off morbidity and mortality on the part of the patient. Such trade-offs will only be eliminated when better understanding and therapy of the disease are available.

Introduction

Success in the treatment of adult acute myelocytic leukemia has lessened the controversy over the decision whether or not to even embark upon therapy for this disease. The previously dismal results of chemotherapy had led to the conclusion that the emotional, physical and financial demands of such regimens were indefensible vis-a-vis the results. However combination chemotherapy with newer and more potent agents has substantially improved remission rates in AML; claims of success have improved from 16% with single agents to 80% with combinations of drugs.[9]

The most effective regimens generally include an anthracycline, a DNA poison, combined with cytosine arabinoside, a pyrimidine analogue. The addition of a third agent, thioguanine, a purine antagonist, is now proferred as the best combination for rapid and tolerable induction therapy although successful induction is attainable with only two of these three drugs.[21] The aim of induction therapy is the elimination of all evidence of leukemia from the peripheral blood and bone marrow. To accomplish this, varying time schedules of drug administration are employed, such as three daily injections of the anthracycline, daunomycin, and seven to nine days of twice daily cytosine arabinoside and 6-thioguanine. The median time to remission is 30 days with 79% of AML patients treated with DAT achieving that end. The induction is accomplished rapidly and no one has required more than three cycles for achievement of remission status.[10] The prerequisite marrow aplasia is reduced to a tolerable time interval when patients need granulocyte and platelet support because of the near universal occurrence of infection and thrombocytopenia during the two to four-week aplastic period.

A consolidation cycle is included in most regimens; a smaller amount of the original successful induction drugs is administered at a 14-21 day interval following documentation of a complete (no marrow evidence of leukemia) or partial (minimal evidence of leukemia, 5-25% marrow blasts) remission. The purpose of such consolidation cycles is to further reduce the leukemic cell mass which persists even into a complete remission; the latter may be achieved with the reduction of three logs in the 10^{12} cell mass present in acute leukemia on presentation Only the tip of the leukemic iceberg need be removed to eliminate clinical evidence of leukemia. But consolidation cycles have constituted a less than definitive attempt at eliminating the total remaining leukemic cell population numbering as many as 10^9 cells.[18]

The almost universal lack of success in curing AML is likely attributable to the persistence of large numbers of malignant cells even with a complete marrow remission. Although recent regimens have met with greatly improved induction success, the median survival in AML is still only 19 to 24 months in most series.[8] The experience in childhood acute lymphoblastic leukemia (ALL) where a 50-60% five-year survival is possible has nowhere been approached in AML. Much of the success in the cure of ALL is attributable to maintenance chemotherapy regimens consisting of cycles of additional drugs administered intermittently for periods of two to three years post-induction. The necessary and successful role of maintenance therapy in ALL is still unsettled in the case of AML. Slightly longer median survivals with current maintenance therapy in AML may perhaps be attributable to the administration of more vigorous induction regimens and larger initial though incomplete tissue kills.[11]

Cure of the disease is contingent upon elimination of all the leukemia. Current protocols mollify their chemotherapy once remission has been attained; others

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have introduced late intensification regimens with claims of prolonged survival and increasing cure rate.[7] But the dismal results of most approaches have led some authors to conclude that chemotherapy will not be the solution for AML.[12] Because of such nonuniformity of results in the management of a disease that makes major demands upon the patient and the health care team, there are dilemmas in the management of AML at the present time.

Maintenance and Late Intensification Therapy

Successful induction chemotherapy in AML is associated with persistence of leukemia; autopsy studies have demonstrated extramedullary deposits of leukemia cells in AML even though the marrow contains no evidence of leukemia.[16] Abnormal interaction with leukemia-associated inhibitory activity in the sera of patients with remission status is evidence of persistence of leukemia in such individuals. Both these lines of evidence plus the large experience of the need for prolonged maintenance therapy in ALL and lymphoma make a convincing argument for some form of maintenance therapy in AML.

Most leukemia protocols have softened their treatment plans once the exhausting and life-threatening induction phase has been completed. Small amounts of previously unadministered agents are given on a daily, weekly or monthly basis with low-risk taking common to almost all these regimens.[6] The success of such pursuits has been minimal; remission maintenance therapy has prolonged the duration of the first remission by a few months but has not significantly affected survival. Such dismal results do not preclude a role for maintenance therapy; they do indicate that the constituents of current maintenance regimens are not equal to the task asked of them. Newer, more potent drugs are needed in the leukemia drug armamentarium.

With the recognition of the dire prognosis of AML even after a complete remission, the group at the M.D. Anderson Hospital has introduced a late intensification schema (LIT).[3] Antileukemic agents other than those used in induction therapy are given for three courses in escalating doses after the patient has been in remission on maintenance therapy for one year. These patients who subsequently received BCG immunotherapy have had a prolonged survival (median duration of complete remission subsequent to initiation of LIT is greater than 55 months), but greater than 50% have relapsed. Again, there is limited efficacy to the drugs in LIT; an additional caution is the long hospitalization required for such treatment.

The dilemma in regard to maintenance therapy in leukemia is that posed by the inadequacy of drugs in the treatment of AML. Pharmacologic research may permit an end to the quandary regarding the amount and type of maintenance therapy needed to cure the disease. This will only be possible when more effective drugs are available. Until that time, different combinations of agents in control studies and more aggressive treatment will constitute the likely approach to maintenance therapy in AML.

Immunotherapy in AML

Enhancement of leukemia cell kill by the addition of immunotherapy to standard chemotherapeutic regimens has been demonstrated in mice models with L1210 leukemia.[13] Unfortunately, a convincing role for immunotherapy has not been demonstrated in human AML, although there is a suggestion of merit to such an approach. The lack of any dramatic inpact with immunotherapy may have its explanation in a phenomenon well described in the L1210 mice model; as the tumor burden thrust upon the immunologic policing gets larger, augmentation of the cure rate with immunotherapy becomes less possible. The inadequacy of current chemotherapeutic regimens in eliminating the majority of leukemic cells in AML may destroy any possibility of a role for immunotherapy in curing this disease.

Contributing to the controversy over immunotherapy is the lack of any standardization of the antigen or its administration. Allogeneic and autologous leukemia cells, irradiated and/or neuraminidase treated (removes sialic acid from cell surfaces and increases antigenicity) are used in several combinations, concentrations, frequencies and locations.[15] The importance of the many variables is apparent from Holland et al. chemotherapy trials.[13] His group, using neuraminidase treated cells, has demonstrated a significant increase in the number of AML survivors and the duration of their survival. The addition of MER, a methanol extraction residue of BCG, to cell therapy produced no prolongation of survival over controls receiving chemotherapy alone. The addition of the nonspecific immunologic stimulus of MER may have compromised the immunizing effect of the cells, perhaps by inducing a suppressor cell inhibition of the desired leukemic policing.

A consensus regarding the role of immunotherapy in AML is not yet available;[1] it awaits the results of carefully controlled studies to demonstrate its efficacy. More basic knowledge of the complicated interaction of the constituents of the immune system in leukemic states may define a better role for immunotherapy in this disease.

Bone Marrow Transplantation (BMT) in AML

Most chemoimmunotherapy regimens for AML are successful in palliation but not in cure of the disease. The latter awaits a solution which transplantation may offer to those individuals with acute leukemia who have an HLA identical sibling. Unfortunately, such compatibility is available only in identical twins and in one out of four siblings. But a suitable donor still does not guarantee success; acute interstitial pneumonia, acute and chronic graft-versus-host disease, recurrence of leukemia in the donor and recipient cells all mar the results of this onerous undertaking. Still BMT of allogeneic marrow (marrow derived from a sibling) does offer an opportunity for prolonged, complete remission and cure in AML.[4,10]

The implications of the availability of such a treatment modality as BMT is that patients and family should be tissue typed at the time of patient presentation with the disease. If a potential matched donor is identified, a difficult decision is then posed in management. Transplantation in relapse is associated with an almost universally unsuccessful outcome. The best results have been obtained in AML patients in their first remission.[19] A move to BMT at this time improves the odds for a successful result but death may occur in the undertaking. However, to defer the decision or the undertaking may eliminate any possibility of a future successful transplant.

Because of the problems of graft-versus-host in allogeneic bone marrow transplants, some investigators have attempted to use the patient's own remission marrow for autologous transplants.[5] The rejection problems are avoided but almost inevitably, failure is the result. Remission marrows are not totally free of leukemic cells even though there is no histologic evidence of their presence. The autologous marrow contains the seed for repopulation of the marrow with the original culprit leukemia cells.

The dilemma that BMT creates in AML management is obvious. It offers a modicum of hope for cure of the disease to a small percentage of such patients with matched donors. An enthusiastic support for its role in AML awaits better understanding of the immunologic features of graft-versus-host which now greatly limits the successful application of BMT.

The Future

The presence of dilemmas makes clinical decisions difficult but they also serve as gadflies for finding solutions to the problem. At the present time the successful induction remission rate and the survival associated with such remissions represent extraordinary progress from the grim, rapid and lethal outcome of AML only a short time ago. The future may contain additional leaps in the field of treatment of leukemia. At the present time *in vitro* agar[20] or methylcellulose cultures[2] of leukemia cells are providing information on the mechanism of cell controls and differentiation; a practical application of these culture systems may be prediction of *in vivo* drug sensitivity analogous to antibiotic testing in bacteriology. Banding techniques have improved the ability to identify chromosomal abnormalities in leukemic cells and these markers together with new immunologic and enzymatic techniques may allow better prognostic and treatment indices to be developed. The support system in leukemia—granulocyte, platelet, red cell transfusions; sophisticated use of antibiotics in the leukoneutropenic patient—all continue to improve.[14,17]

A cure however does not appear imminent. The clinician is still confronted by a disease that resists cure in most cases. Research as to the cause of leukemia and methods to cure the disease must be actively pursued. These are the only long-term solutions to the dilemmas that now confront the physician caring for patients with AML.

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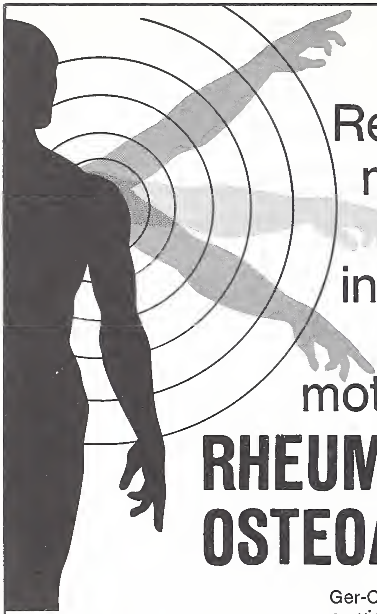

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Preventive Chemotherapy for Tuberculosis: A Good Thing Overdone?

HANS H. NEUMANN, M.D.

ABSTRACT—As the incidence of active tuberculosis continues its steady decline, epidemiological control measures require occasional review. Mass chest-film surveys have been discontinued years ago and periodic re-screening of non-reactors to tuberculin is no longer widely done. A surviving control measure is preventive chemotherapy. While some indications for this procedure remain, such as positive skin tests in children or among those with complicating pathology, there seems to be little justification for its use in reactors or converters found by chance, in random surveys. With specific exceptions, proportionately too few mycobacterial carriers develop active disease, to warrant the risks and nuisance linked to a year's preventive therapy requiring close medical supervision.

Measures to control a retreating disease require occasional review in order to decide what is worth doing and what is better left undone. As the number of tuberculosis cases in the U.S. continues to decline, some control policies that were useful in years past become ineffective, uneconomical, unnecessarily hazardous or burdensome. Yet procedures which at best, are of little merit, and at worst, may do some harm, continue to be in use. Many organizations, schools and institutions still require chest x-ray screening of everyone from whom they can demand it.

One of the surviving control measures is preventive chemotherapy for persons assumed to be at risk which still includes randomly found tuberculin reactors and "recent converters". Numerically, these constitute a large segment of all candidates for preventive treatment. Although the idea of preventive chemotherapy may be appealing, updated, objective, statistical evidence is called for to show that its benefits still outweigh the problems inherent in the procedure.

The rate of tuberculosis deaths per 100,000 in the U.S. declined from 15 per 100,000 in 1950 to 6 in 1960, to 2.6 in 1970 and it is now below 1.4 per 100,000.[1] For the white female it is less than half that figure. According to the results of tuberculin tests reported in 1977 for 36 states, the number of positive tuberculin reactors is still considerable. Four percent of 2,738,915 persons were found to be positive reactors.[2] While in larger cities, the figure is over 8 percent, the overall rate of reactors for all age groups in the U.S. is lower, perhaps 2 to 3 percent, or 2,000 to 3,000 reactors per 100,000 of population. The rate of bacteriologically confirmed new cases of tuberculosis was 10 per 100,000 in the same year.[3] Thus, there were 10 active cases per 2,000 to 3,000 positive reactors, a rather low ratio. Moreover the ten activations include those with predisposing lung disease like silicosis, activation in the cachectic or the old, the immunosuppressed and the alcoholic.

If all age groups are included, the rate of positive reactors among the residents of major cities may range from 1 to 3 percent in school children, to 30 to 40 percent for those 65 years of age and older. The New Haven School System has over 24,000 students. Comprehensive tuberculin testing showed an overall reactor of one percent. Under such circumstances of low yield, it is now acceptable practice to discontinue further routine testing. Thus, about 240 untested and unidentified positive reactors remain untreated. These reactors, leaving school year after year, become part of the much larger number of reactors among the middle-aged and the elderly who never received preventive treatment.

Based on partial surveys in 1979, the number of reactors in New Haven, a city of 135,000 is still about 9,000 for all age groups. Most of these were never treated preventively. Despite this, the incidence of new

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active cases is below 20 cases per year.

Having experienced one year without death from tuberculosis and with one death from Isoniazid, the figures and ratios suggest reconsideration of our current tuberculosis control policies by foregoing those that are burdensome or with potential noxious effects, just as mass screening by chest x-rays was discontinued when the adverse effects of radiation began to outweigh the public health benefits.

Prevention with Chemotherapy

In deciding the issue of tuberculosis prevention, medicine is trying to straddle the fence between what is desirable for the individual and what is epidemiologically useful. If, for the individual skin reactor, the probability of a need for preventive chemotherapy is remote, from the angle of public health, the protective value of treating reactors discovered by chance, is minimal, since only a minute segment of all reactors is "apprehended" for preventive therapy. In the past, as we abandoned tuberculosis control procedures one by one, a question arose each time concerning a temporary, possible increase in risks for the community. They never materialized, even though each procedure including chemoprophylaxis had undoubtedly contributed to the decline of tuberculosis.

There is little justification in penalizing a small segment of randomly found reactors if there are 50 or 100 times as many other reactors in a community who remained undetected. Preventive therapy for one year, provided under close medical supervision is to some degree, stigmatizing and certainly burdensome. It carries a small, but nonetheless real risk of injury to the liver, of a variety of other, troublesome, more rarely encountered side effects and of death.[4,5] Nationwide, over 30 percent of the persons with positive tuberculin tests who started preventive chemotherapy discontinued medication, on medical advice or for various other reasons.[6]

Preventive treatment reduces the risk of developing endogenous disease from past infection, but it does not eliminate it, nor that of acquiring tuberculosis. In the skin reactor, bacteriological confirmation of infection and of its response to treatment is not possible by culture. We may be involved in long term treatment of something that is not tuberculosis in the first place.

Prevention and the "Converter"

The concept of treating "recent converters" should be reviewed as well, first because now that the routine of annual skin testing has been widely abandoned, it will be difficult to know who most of these recent converters are. Moreover, all presently positive reactors were at one time "recent" converters, not identified at the time of conversion; and most of them got by without developing active disease in the year of conversion. The criteria by which a high active-disease incidence in recent converters were determined in the past, may no longer conform to current, more demanding diagnositc standards. In searching for converters, there are sources of error by comparing tuberculin skin tests taken on two occasions. These include differences in techniques and in skills, in the product used, in the presence of a "booster effect" of the first inoculation, and other factors.

Educated people such as nurses, physicians, or teachers, or those who conscientiously undergo annual physical examinations are the reactors more likely to come to medical attention. They can be made aware that the probability of developing actual disease is remote, and be alerted to the symptoms should they ever develop. They can have occasional chest films, though even these are unneeded in most cases.

The uneducated, asymptomatic converter or reactor without disease is less likely to be found in the first place, and compliance with a prescribed drug regimen for one year often poses problems. Treatment of members of low socio-economic level, without disease or symptoms, often achieves only haphazard adherence to a program—with its inherent risk of producing drug resistant organisms. The apparently healthy is unimpressed with the need for long term preventive treatment.

Continuing Prevention Methods

A public health risk arises from infectious patients who are not socially responsible because of personality disorders or alcoholism.[7] It is these who require fullest attention to prevent their spreading the infection. Others for whom decisions must be made on an individual basis, are asymptomatic household contacts to patients with active tuberculosis, though controlled studies may re-evaluate the need for chemoprophylaxis versus close follow-up. Even immediate household contacts do not necessarily get infected. Still, search for infections in the environment of a new case of tuberculosis remains as in the past, a most valuable public health measure.

Decisions to treat randomly found reactors preventively, should be based on conservative medical judgment. Undoubtedly there remain a number of definite indications for preventive chemotherapy. These include positive skin reactions in children or if combined with specific diseases, such as silicosis or immunodeficiencies. Industrial workers exposed to dust, such as coal miners and steel workers, are in this category. If they develop pulmonary disease it overshadows the tuberculosis. But even this type of tuberculosis rarely spreads except to other predisposed patients such as those with silicosis.

In other environments, tuberculosis has a low infectivity. Nowadays, physicians and hospital staffs can work quite safely with tuberculosis patients. If a state of infection ensues, as evidenced by positive skin reaction, this, in turn, has a low probability of developing into active disease. And if disease does develop, it can effectively be treated in the responsible patient. At present, the rate of new tuberculin reactors in the American economic middle-class is low. They are more likely to be detected and treated preventively but it is not this factor that keeps the incidence of disease low in this group, since even among these the percentage of all reactors coming to medical attention and receiving preventive chemotherapy is small.

Policies for preventive services to the poor and to specific ethnic groups are another more complicated matter.[8] In New Haven, in a calculation of the annual risk for various population groups, we found ratios of one new active case of tuberculosis for 4,200 male and female white tuberculin reactors of all ages; one in 3,250 for all female reactors, regardless of race; one in 750 white male reactors; one in 525 nonwhite female reactors but one in 175 nonwhite male reactors.[9] Thus, statistics compiled from summaries of tuberculosis incidence in all social strata should not be projected in setting overall strategies of tuberculosis control, considering the varying problems of detection, susceptibility and compliance in different population segments.

Tuberculosis is no longer epidemic, as it was earlier this century, and it is no longer endemic. It has become a sporadic disease. Under these circumstances of declining incidence, it may become necessary to remind physicians that tuberculosis still exists, and to impress on them the need to test the symptomatic or any case even remotely suggestive of this infection. Conversely, considerable thought should be given before putting a mere reactor, without evidence of disease, on chemoprophylaxis with its own set of hazards.

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On Human Experimentation

Have we a right to perform experiments and vivisections on man? Physicians make therapeutic experiments daily on their patients, and surgeons perform vivisections daily on their subjects. Experiments, then, may be performed on man, but within what limits? It is our duty and our right to perform an experiment on man whenever it can save his life, cure him or gain him some personal benefit. The principle of medical and surgical morality, therefore, consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, i.e., to the health of others. But performing experiments and operations exclusively from the point of view of the patient's own advantage does not prevent their turning out profitably to science. It cannot indeed be otherwise; an old physician who has often administered drugs and treated many patients is more experienced, that is, he will experiment better on new patients, because he has learned from experiments made on others. A surgeon who has performed operations on different kinds of patients learns and perfects himself experimentally. Instruction comes only through experience.

—Claude Bernard, *An Introduction to the Study of Experimental Medicine,* 1865.

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Ten weekly workshop sessions cover topics in cardiology, hypertension, endocrinology and metabolism, hematology, pulmonary diseases, rheumatology, infectious diseases and gastroenterology. Patient problems are based on actual case presentations with case protocols given to registrants for home study in advance of the session. Instructors analyze the cases giving their views on differential diagnosis and approaches to treatment with registrants participating in the discussion. Sessions are informal and physicians are invited to submit problem cases from their practices for discussion. A distinguished faculty of clinicians drawn from the Department of Medicine participate in the course.

30 Category I credit hours; 30 AAFP prescribed credit hours (pending)

Also . . .

CLINICAL TUTORIAL — 152. Dermatology For The Practicing Physician

Wednesdays, 1:30 to 3:30 P.M. September 24 to October 22, 1980

David L. Ramsay, M.D., Associate Professor of Dermatology

Specifically designed for non-dermatologist physicians, especially those involved in primary care practice. Major emphasis is on unraveling diagnostic possibilities in a presenting dermatological complaint and providing practical guidelines for relieving the patient's symptoms and promoting resolution while the evaluation is proceeding. Special attention is given to the most commonly encountered dermatological problems in general office practice. Teaching includes lectures, case presentations, group discussion and a forum for presenting specific diagnostic and management problems from the registrant's practice.

10 Category 1 credit hours; 10 AAFP prescribed credit hours (pending)

CLINICAL TUTORIAL — 300. Introduction to Non-Invasive Cardiovascular Diagnosis

Wednesdays, 1:30 to 3:30 P.M. October 29 to December 3, 1980
(No session November 26)

Dr. Itzhak Kronzon, M.D., Associate Professor of Clinical Medicine

This course is for the non-cardiologist physician. It provides clear and specific guidelines for the application of non-invasive diagnostic procedures in ambulatory and hospital practice to assist the physician in properly ordering and sequencing these examinations, in interpreting reports from consultants and in better understanding the clinical literature. Each presentation begins with a clear description of the physical principles underlying the procedure. This is followed by a review of indications, contraindications and test limitations. There is a comparison of information from non-invasive with invasive (catheterization) procedures with special reference to the value of the information in patient management as well as risks, costs and patient suffering. Case studies illustrate how non-invasive procedures are applied, their proper sequence in the diagnostic work-up and in their interpretation. The instrumentation for each procedure is described and demonstrated and there are review practice sessions for interpreting diagnostic data. Topics include: Basic Concepts of M-Mode Echocardiography including Recognition of Valvular, Congenital and Pericardial Disease and Cardiomyophathies; Radionuclides including the Evaluation of Cardiac Performance and the Recognition of Ischemic Disorders; Holter Monitoring; Systolic Time Intervals; Phonocardiography, Apexcardiography and Arterial and Venous Tracings; When to invade: The Limitations of Non-Invasive Cardiology; Stress Testing; Dynamic Imaging. This course does not require any previous familiarity with non-invasive cardiology.

10 Category 1 credit hours; 10 AAFP prescribed credit hours (pending)

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Course 300. Introduction to Non-Invasive Vascular Diagnosis: $145.00

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CN 7/80

CSMS – AEtna Malpractice Program

1979—1980 Semi-Annual Report

FRANCIS P. GINTY

This report is a summary of some of the areas of interest of concern to the Society and the Company at the second half of the 9th Account Year.

I. EXPERIENCE

For purposes of continuity of data analysis, the format of prior reports is retained. Exhibit 1, below, reflects loss activity through the second quarter of the Account Year, based on a 4-1-80 valuation date. Six months ago we reported the number of arising claims or suits was 1,515, an increase of 14.7% over the prior six-month period. At present, *1,616* claims have been made—an increase of 101 cases or 7% in the last six months. The past year reflects an increase in arising claims of *296* for an increase of *22%*. This represents a slight moderation in the percentage of rising claims. From these figures it can be concluded that there has been no significant abatement in the frequency of claims.

Exhibit 1
LOSS ACTIVITY

Account Year	*Incurred Losses*	*Arising Claims*	*Open Claims*
1971	$ 1,562,020	111	5
1972	3,441,685	208	29
1973	2,914,075	221	49
1974	3,341,506	268	71
1975	6,930,237	274	97
1976	4,412,735	267	128
1977	3,334,494	147	79
1978	2,614,019	110	62
1979 (6 mos)	87,632	10	7
TOTAL	$28,638,224	1,616	527

The *unloaded* loss experience has increased by $3,075,838 in the last six months. Combined with a six million dollar increase in the prior period, losses have increased *$9,040,456* or *46%* in the past year. These latest loss dollars account for one-third of the total loss experience in eight and a half years of the program. Over the last 24 months, the average cost per claim (severity), including those closed without payment has increased from $10,154 to $12,500 to $14,836 to a present average cost of *$17,710*. In a single year the average cost has increased by $5200 a claim, compared with average cost increases of $2200 in the earlier years.

This data suggests the dollars required to dispose of claims far exceed other cost increases reflected in the inflationary spiral. The losses for the 1975 Account Year are presently valued at $1,000,000 higher than a year ago, while a single case opened in April has an initial reserve of $1,500,000. The deterioration of program experience noted in 1978 and 1979 has continued at a dangerously accelerating rate into 1980.

II. INCIDENT REPORTING

The process of tracking claim activity is an ongoing responsibility of the Account Supervisor. In terms of numbers, the emphasis in claim and suit activity continues to focus on the specialities of obstetrics, orthopedics, general surgery, and anesthesia. We are also seeing increasing numbers of cases against medical practitioners, including general practitioners and internists for missed diagnosis, e.g. cancer. The character of these claims generally results in higher exposures due to injury and more claim dollars expended to dispose of those which have merit. This activity is reflected in the higher premiums paid by these classes of physicians.

Exhibit 2 is a reflection of the effect of the "long-tail", the phenomenon accountable for the volatility of the malpractice line of insurance. Trending for frequency and severity of claims is made more difficult for actuaries in the pricing of the product, due in large measure to the delay in reporting actual or potential claims to the AEtna.

We and the Society have repeatedly stressed the

MR. FRANCIS P. GINTY, AEtna Administrator for the CSMS Professional Liability Program, now in its eighth year of existence. *This report was issued to the CSMS Committee on Professional Liability in June, 1980.*

Exhibit 2

"THE LONG TAIL": CLAIMS REPORTED BY 4/80

Account Year	*1971*		*1972*		*1973*		*1974*		*1975*		*1976*		*1977*		*1978*		*1979*
	4/72	*10/72*	*4/73*	*10/73*	*4/74*	*10/74*	*4/75*	*10/75*	*4/76*	*10/76*	*4/77*	*10/77*	*4/78*	*10/78*	*4/79*	*10/79*	*4/80*
10-1-71/72	7	35	54	67	78	93	101	103	108	106	107	106	108	111	111	111	111
10-1-72/73			16	54	100	123	153	182	191	198	199	204	206	207	207	208	208
10-1-73/74					19	49	82	111	160	198	209	217	220	220	220	221	221
10-1-74/75							25	76	133	158	198	241	255	262	264	267	268
10-1-75/76									12	55	166	139	182	257	255	269	274
10-1-76/77											22	56	94	129	185	254	267
10-1-77/78													10	41	64	107	147
10-1-78/79															15	78	110
10-1-79/80																	10
TOTAL ARISING CLAIMS								472	604	755	841	963	1075	1207	1321	1515	1616

importance of advising the Company, as soon as practicable, of any untoward or unexpected result in the management of the patient. This is a contractual obligation. An individual physician's premium does *not* go up if a claim is reported. Many months after the event occurred, the odds are that ultimately the doctor will be forced to report that he has been sued.

This delay makes investigation and evaluation of the claims more difficult due to impaired memories and poorer records. The result is a high cost in the disposition of claims due to the time lag, inflation, etc. as demonstrated by the data above concerning the increased severity of claims.

Six months ago the average reporting time to the AEtna under the CSMS program was 14 months, and the gap continues to grow. We can predict with a reasonable degree of accuracy that the 1979 Account Year will ultimately produce approximately 275 cases. And yet, with half the year over, only *10* cases have been reported! The "cockeyed optimism" of physicians that the problem will go away, is nurtured by the deliberate delay of patient's counsel to act. They often wait until just before the Statute of Limitations runs out to bring suit. Meanwhile, they have had two to three years to perfect a case against the defendant by expert review of the records and identification of expert witnesses. Meanwhile the AEtna waits with concern and certain knowledge that those cases are out there; but as yet they remain unidentified.

By far, the easiest contribution the individual doctor can make to control losses and increased premium is early communication with AEtna's Claim Department.

III. CLAIM CLIMATE

One year ago there were only 441 cases *open* in the program. This increased to 508 at the end of the 1978 Account Year—an increase of 15%. At present there are *527* cases open, for an increase of only *4%*. In the first six months of the past year the number of lawsuits *pending* increased by *29%*. In the last six months the number outstanding has increased from 494 to 525, an increase of only *6%*. Controlling the ratio of outstanding cases to arising is the paramount concern of every insurance company claim department. Concentration by AEtna on malpractice claims has had the desirable effect of controlling the number of cases which remain open; but in the face of increasing costs of disposition, program results continue to deteriorate.

Earlier reports had reflected the belief that the downturn of claim activity in 1976 and 1977 was due in part to the cyclical character of malpractice litigation. Also, the high media interest in malpractice and the rash of legislative attempts to provide solutions may have given some attorneys incentive to bide their time, cautiously waiting to see what effect tort reform would have before resuming the offensive again. The hiatus may well have ended.

A growing ingenuity on the part of plaintiff's attorneys in bringing malpractice suits is being matched by a corresponding willingness on the part of the courts to accept more novel theories of law. Further, the notably higher verdicts in Connecticut are expected to continue to increase, due to the inflationary cost of health care and the reluctance of the courts to conclude that the verdicts are other than reasonable when compared with the injury. We can expect this element will motivate attorneys to seek out and select high damage potential cases, especially those involving birth defects and injuries.

There are other reasons why the "experts" have predicted an upswing in the number of claims in the early '80's. The economy's inflationary spiral is credited with being another contributor. With a pinch in their pocketbooks, the consumer begins to look harder for new sources of money—and one of these sources is potential litigation.

Most of the problems which gave rise to the medical liability crisis in the middle '70's have not really changed.

We still have the same social problems, an expanded medical technology, the dissociation between doctors and patient, and a sense of alienation on the part of patients. Better informed medically, they have been taught that for every wrong there must be a remedy. They will continue to pursue it.

IV. LEGISLATIVE ACTIVITY

Efforts at tort reform have had an impact in some areas of the country, notably in California. But constitutional challenges have weakened or threatened such legislation in many other states. An analysis of the existing statutory enactments and the body of common law in Connecticut reflects a situation somewhat more favorable to physicians than in other states.

The Society as a proponent of new legislation, must face the usual resistance of legislatures to change the common law. This hesitancy is well founded in principle though it is sometimes the basis for misunderstanding on the part of some physicians as well as the general population. This is not meant to infer that the legislative route to changes of existing laws or pursuit of new ones concerning malpractice is an inappropriate avenue to pursue. The Society has recognized such pursuit may not result in immediate mitigation of the existing dilemma. Nevertheless the changes that may occur as a result of seeking the aid of the legislature may be significant and should not be overlooked. To this end the Society, CHA, and the AEtna continue to meet each December, before the legislature convenes, to consider appropriate action.

Among the measures considered this past year were a "Collateral source" provision that would prevent a plaintiff from collecting an amount equal to the cost of health care as part of compensatory damages, if this amount has already been paid by a third-party carrier. It was agreed these sums should be simply evidence allowed for the jury to consider and not a bar to recovery.

A second bill considered will allow for a malpractice judgment to be satisfied by structured settlements in periodic payments. The intent is to revert funds in the event of death, and to prevent windfall profit to others than the patient.

Pursuit of these bills and a mandatory screening process was postponed by agreement with the Hospital Association. Practical considerations dictated the likelihood these bills would not pass in this last session of the General Assembly. Instead, attention focused on unfavorable interpretation of the Peer Review Immunity Statute (sponsored by the Society in 1976) by lower court decision and rulings on trial testimony. Through the effective lobbying efforts of CSMS and CHA, an entirely satisfactory compromise revision of the Statute passed by the legislature and is now law.

New year appropriate options for continued tort reform, including preservation of the present Statutes, will be explored, evaluated and considered in formulation of a joint legislative package.

V. CLAIM DEFENSE PANELS

The mechanism of peer review is the single most effective tool to assess the practical aspects of the impact of patient injury on loss dollars paid under the program. The first section of this report reflected the present average cost per claim, (including open cases, closed cases paid, and cases closed without payment) amounts to approximately $18,000 at present.

The cases reviewed by the panels have generally had the potential for higher exposure than the average case. A review of the cases disposed of to date reflects payments totaling $10,074,763. This represents an average payment of $66,281. Payments made on only 152 cases represent more than one-third of the total loss dollars under the program. A single case was settled for 1.3 million dollars.

With some 1600 cases to date, *371* have been presented to panels of 20-25 doctors for in-depth analysis of the clinical aspects of each case. More than 850 Connecticut doctors have participated in one or more panels. The vote continues to reflect that approximately half these cases have some merit on the medical facts alone and should be settled. To date, *210* cases have been settled (40%), withdrawn (10%) or tried (7%), leaving *161* (43%) pending trial or disposition.

For obvious reasons, the cases selected for panel review present questions of fact to counsel for the defendants and to AEtna's Claim Department.

Further, they present the unique opportunity to evaluate a physician's witness potential, as well as his ability to defend himself before a unique forum—the jury of his peers.

Lastly, the panels embody the partnership spirit of the program by providing physicians the opportunity to share in the responsibility for the disposition of the cases. The Society will continue to draw on more physician's participation to provide education and assure continuity of the process.

VI. LOSS CONTROL AND EDUCATION

AEtna's Loss Control and Education Program was initiated coincident with the beginning of the CSMS Professional Liability Program in 1971. It was developed and evolved from a mutual concern on the part of the Society and the AEtna for the rising number of claims and the increasing severity of losses. Its tools include the use of video tapes, printed materials, speakers, special studies, claim tracking and analysis, and claim review panels—all directed at identification of the causes and prevention of malpractice.

Traditionally it has been extremely difficult to "sell" injury prevention programs to health care providers, especially physicians. Many doctors look at formal injury prevention programs as an unneeded burden on an already overworked practice. And yet, 80% of all claims made by, and 84% of all claims paid to patients result from injuries which occur in hospitals—the traditional locus for medical education. Many of the programs provided deal with rare and highly specialized conditions and diseases; but the malpractice pandemic causes more sorrow in this country than these other uncommonly encountered entitites.

The standards review organizations and a growing body of law have now imposed on hospital trustees the responsibility to strengthen physician and administration determination to improve and control quality of care by setting up a system of risk management. Essential to such a system is an understanding of health care delivery in each institution, including a review of data (financial and otherwise) which pertain to liability claims.

The belief that malpractice circumstances have underlying principles that are subject to quality control and are preventable, has provided the motivation for adoption of a Patient Injury Program by the Society's Committee on Professional Liability. Outlined in the last semi-annual report, it is an obvious and essential component of the mandated Quality Assurance programs presently being drafted in all hospitals. Malpractice data supplied by AEtna can be used as a sensor to trigger audit, evaluation of clinical data from patient charts, and assessment of the potential for occurrence. The primary objective of the process is to effect performance change through management principles. Introduction of the program through medical staff leadership was the first step, with four dinner meetings throughout the State in May and June.

The Society and AEtna must now look to the physicians to voluntarily undertake a role in implementing the process. If behavior modification or real change is to occur, it is not enough to mandate a quality assurance process. The concept needs cooperation, commitment, patience, skill and insight to reach the moment when the individual's willingness to change results.

The monkey is now clearly on the physician's back, where it belongs, to work with hospital administration in reducing patient injuries and their foreseeable consequence, malpractice litigation.

VII. CONCLUSION

This report has attempted to refocus attention on the contributing causes of the exacerbated malpractice situation—and they are manifold. The comments and statements are gratuitous and perhaps self-serving. But rightly so. The AEtna is genuinely concerned for the future. The malpractice problem of the '70's has left an indelible mark on American medicine. Many solutions have been proffered in the past, but few with real merit.

The problem will be much closer to resolution when helath care providers become more aware of methods to avoid risks and prevent injury and learn how to implement those methods and practices. As medicine enters the '80's this is one goal toward which to strive. Connecticut's physicians should grasp the opportunity to reach that goal with commitment and hard work.

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Extended Hospital Stays: A Growing Problem

JOHN T. LYNCH, M.P.H.

ABSTRACT—During 1979, Connecticut's thirty-six general hospitals completed a survey of extended hospital stays due to problems of placing patients in skilled nursing facilities (SNF) and intermediate care facilities (ICF). From June to December, the extra days of hospitalization rose from 4,035 to 6,034 days. The placement problems were most pronounced in northwestern and southwestern Connecticut, although most of the state exhibited some degree of placement problems. The extended stays represent a yearly cost of $8.7 million for inpatient stays. These costs involve patients, mostly elderly, who medically no longer require hospital care, but who nevertheless remain in the hospital because there are no nursing home beds available to which they could be transferred or because they have not yet been certified by the state as eligible for Medicaid assistance for nursing home care. If the shortage could be eliminated and the certification process expedited, as much as 72.4% or $6.3 million of the $8.7 million could likely be saved. This savings represents the difference between hospital rates compared to nursing home rates.

Introduction

Connecticut short-term hospitals and Professional Standards Review Organizations (PSROs) have noticed increasing difficulties in the placement of patients into skilled nursing facilities (SNF) and intermediate care facilities (ICF) during the past year. These placement problems have inhibited efforts to reduce the length of patient hospital stays and thus reduce costs. In order to define the magnitude of the problem, the Connecticut Hospital Association (CHA) conducted two surveys—a preliminary one in June, 1979, and a more detailed one from November 15 through December 15, 1979. The surveys, involving hospital discharge planning, social service and utilization review departments, recorded daily the number of new placement cases and the number of patient days being generated while awaiting final placements. Results were compiled by CHA.

Results

CHA's second survey showed that from November 15 through December 15, 784 cases required placement, and these patients waited 6,034 days until they were finally placed. These extended hospital stays represented 2.3% of all hospital medical-surgical and psychiatric days, and averaged 7.7 extra days per placement case, although some individual patients waited as many as 30 days for placement. The extended stays were not uniformly distributed throughout the state. Health Systems Areas I and V (southwestern and northwestern Connecticut) exhibited the largest number of patient days, 2,093 and 1,802 days respectively.

Based on hospital service area share percentages, individual hospital data was charted to represent all Connecticut towns. Although there are more total extended stays in the southwestern region of the state, as a function of size of population and total number of adult hospital days, the greatest impact is being felt in the Danbury, New Milford, and Sharon hospital areas. Other areas seem low in comparison, but still face their own problems. During the study, a new facility opened up in the Griffin Hospital area, causing this hospital's service to appear as relatively problem-free. Now that the new facility is filling up, problems in that area are occurring as well. Just as opening a new facility affects an area, so too can facility closure or delicensure have an exacerbating effect. Although there may be legitimate reasons for such closures, one effect which can't be avoided is a loss of SNF beds.

JOHN T. LYNCH, M.P.H. is associate vice president, data applications at the Connecticut Hospital Association (CHA) in Wallingford. Mr. Lynch earned his undergraduate and graduate degrees at Yale University and is also the author of the 1978 CHA study on the impact of Connecticut's aging population on hospital bed needs.

A comparison of the preliminary study done in June and November-December survey data indicates that the extra days of hospitalization have increased almost 50% from 4,035 in June to 6,034 in November-December. This large increase is due to a combination of factors which include an aged population that is growing in size and the deinstitutionalization of state mental retardation of psychiatric patients. Continued study is needed to see if this increase will continue.

Because the population is aging, the number of placement cases will increase substantially in the coming years. Population projections published by the Connecticut Department of Health Services show that the number of elderly over age 74 will increase by almost 48,888 over the next 20 years, from 112,463 to 160,385.

This aging of the population represents an increase of 42.6% from 1980 to the year 2000. This percentage increase in the over-age-74 population also mirrors the potential increased need for SNF and ICF placements, and potential increase in hospital spending for such extended stays. However, SNF and ICF construction is not keeping pace with the over-age-74 population growth. Another factor adding to the problem is the deinstitutionalization of state mental retardation and psychiatric patients, since these patients are now occupying nursing home beds in many cases.

Conservatively, if the 6,034 extra days a month are assumed to be a twelve-month average (rather than assuming a continued 50% increase every six months) the extended stays represent over 72,400 patient days and $8.7 million a year at the $120/day average Connecticut hospital Medicaid room and board rate. Compared to the $120/day hospital Medicaid rate, SNFs average about $33/day, representing a potential savings to Medicaid of $87/day. The June study showed that 44.5% of the extended hospital days were either from Medicaid patients or from patients awaiting Title XIX eligibility certification. Taking this $87 difference between inpatient and SNF daily rates, Medicaid alone could save almost $3 million a year if only the certification process could be expedited and there were more SNF and ICF beds available.

Impact on Community Hospitals

The increasing number of hospital days being generated by patients awaiting placement has a dramatic impact on hospitals. The extended days add costs—nearly $8.7 million—that inhibit hospital management's efforts at cost containment.

Additional manpower also has to be added, especially in areas of discharge planning and social services, in order to cope with the increasing difficulties of patient placement. Cash flow is a major problem to the hospital. Payment for Medicaid patients is slower than for any other third party payor.

Hospital swing units (nursing units which alternately may be occupied by either acute care or SNF patients) are not now permitted by the Medicare/Medicaid law, requiring that hospitals staff and equip all hospital beds as if they were occupied by patients requiring acute level of care.

Through utilization review efforts, hospitals are gradually reducing the average length of stay. However, these extended stays have increased the average length of stay from 7.3 to 7.5 days.

Because of the time lag involved in building new nursing home beds, it is likely the problem will become worse during the next one and one-half to three years unless some present sources of the problems, i.e., deinstitutionalization, certification delays, etc., are resolved. One development might be the need for hospitals to build additional beds sooner to meet these extra demands and at a much higher cost than that of SNF beds. After all, 72,400 extra days of hospitalization a year is equal to having a 248-bed hospital at 80% occupancy.

Impact on Patient

Beyond operational problems, the nursing home bed shortage is definitely affecting the hospitals' ability to provide quality patient care. During periods of high occupancy, for example, patients awaiting elective surgery may have their admissions postponed since their beds are being occupied by patients awaiting placement. In addition, a patient awaiting SNF/ICF placement has to deal with feelings of anxiety at a crucial time when such feelings can be harmful. For many, the anxiety is aggravated by official Medicare "denial" letters, notifying them that they are no longer eligible for Medicare hospital benefits.

Sometimes the denial letter is followed by a second letter announcing that the patient is also no longer eligible for skilled nursing care coverage. Still recuperating, the patient is told that s(he) has no choice but to take the first available SNF bed no matter what its perceived quality and no matter how far away it may be from home or family. Although most of the hospitalization costs may have been covered, there is little coverage for SNF days. Still in the hospital, the patient often must come up with $1,000 in advance for a nursing home stay, or apply for welfare. Although hard working and self-sufficient all through life, the patient is reduced to seeking public assistance, or going home to inadequate care. The decision to seek public assistance may require liquidation of all assets, including his/her home, thus forsaking hope of ever going home again. Weak and perhaps disabled physically, the patient is certainly demoralized, dehumanized, and crippled emotionally from such placement problems.

Impact on Families

Comments on the survey have indicated that the patient's family too has few choices for its relative awaiting placement. Can the family afford the time and money to bring the relative home? Should a family member take leave from work to stay home and provide proper care for the patient? How often can the family visit if the patient is placed in a SNF halfway across the state? Is the family physically able to lift, wash, rehabilitate, etc., the relative if brought home? The problem of placement brings such questions to immediate reality.

Some Sources of the Problem

Although not directly studied by the survey, possible sources of the problem mentioned by hospital personnel include:

- Too-low Medicaid SNF reimbursement rates so that there is no adequate profit margin or return on equity. Therefore, owners do not want to expand their facility.
- The time-consuming regulatory approval process has made it too expensive and frustrating for investors to build nursing homes.
- A lack of construction financing by lending institutions.
- Deinstitutionalization of psychiatric and mentally retarded patients from state institutions and subsequent admissions to SNF facilities.
- Use of Connecticut SNF beds by New York Medicaid patients.
- Zoning regulation and high land and labor costs (in Fairfield County) are disincentives for building SNF beds there.
- Not enough intermediate care facilities (ICF) or homes for the aged or home care.
- Slowness of the Title XIX eligibility certification process.
- Limited facilities for the placement of teenagers and young adults with emotional problems, causing this group to generate medically unnecessary hospital days as well.
- A greater percentage of the population in the over-age-74 stage of life.
- Little insurance coverage for SNF stays.

It is important to note that most of the above problems are governmentally induced.

Physicians and the Canadian Insurance Program

Physicians have shifted to more costly patient services under the Canadian insurance program. During the first five years of universal health insurance in Quebec, physicians generally saw fewer patients but leaned toward more expensive patient care. According to research funded by the National Center for Health Services Research (NCHSR), the increase in the cost per patient visit charged by general practitioners and general surgeons was accompanied by a marked shift from ordinary examinations to more costly, complete examinations. At the same time, the number of urgently-needed surgical procedures rose, while the rate of "lower priority" surgical procedures stayed fairly constant, and the number of them performed per physician actually dropped. The introduction of complete health insurance coverage apparently did not affect the relative geographic distribution of physicians in Quebec, but did stimulate an increase in total health care services provided throughout the Province—an indication that more people were receiving medical care. Results of the study, conducted by Mathematica, Inc., of Princeton, New Jersey, are summarized in "Responses of Canadian Physicians to the Introduction of Universal Medical Care Insurance: The First Five Years in Quebec." Copies are available without charge from National Center for Health Services Research, 3700 East-West Highway, Hyattsville, MD 20782.

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The Treatment of Primary Breast Cancer: A Patient's Viewpoint

ROSE KUSHNER

I am delighted to be part of the Consensus Development Conference on "The Treatment of Primary Breast Cancer: Management of Local Disease." This is an important issue to women all over the world, and what the National Institutes of Health will recommend will affect millions of us.

Thank you for asking me to participate.

As far as we women are concerned, there are many reasons this long-standing controversy must finally be resolved.

The most important one, of course, is simply that the search for the "best" treatment for such breast cancer has been going on all over the world for almost a century. Yet no one seems to know what that "best" treatment is. Virtually every country – indeed, in some cases, from institution-to-institution within a city—seems to have a most "popular" or "favorite" way to treat primary, localized breast cancer. As a result, we women have been subjected to a multitude of permutations and combinations of recommended treatments—enough permutations and combinations to make even a Fourth Generation computer develop a short circuit.

What are some of these?

According to a recent preliminary report, "Short Term Patient Care Evaluation Study for Carcinoma of the Female Breast," published by the American College of Surgeons, (12 October, 1978), there were seven surgical procedures used for primary treatment (not counting, "No surgery": 648 cases of 14,634 in this sample) in the United States.

These were listed as:

"Wedge excision (lumpectomy)
Total mastectomy only
Total mastectomy with low axillary dissection
Modified radical mastectomy with full axillary dissection
Radical mastectomy (Halsted type)
Radical mastectomy with internal mammary node biopsy
Super radical with *en bloc* removal of chest wall"

In addition to these surgical procedures reported by the ACS, we women know that there are also others:

Local excision or segmental resection – removal of the mass with a margin of healthy tissue;

Quadrantectomy – removal of a quarter of the breast with no further treatment whatsoever;

Any of the above less-than-mastectomy procedures, followed by irradiation of the breast, chest wall and other areas – if necessary;

The above (lesser surgery plus some type of irradiation), followed by a sampling of the lower axillary nodes;

The above (lesser surgery plus some type of irradiation), followed by a complete *en bloc* axillary dissection;

Simple (or Total) mastectomy without any treatment to the axillary nodes;

Simple (or Total) mastectomy, followed by irradiation of the axilla;

Simple (or Total) mastectomy, followed by a sampling of the axillary nodes. For lack of a better name, this procedure is becoming known as an "extended total mastectomy."

ROSE KUSHNER, Executive Director, Breast Cancer Advisory Center, Kensington, Maryland. Presented before The Consensus Development Conference, The National Institutes of Health, Bethesda, MD on June 5, 1979. Mrs. Kushner is the author of *Breast Cancer: A Personal History and an Investigative Report* (Harcourt Brace Jovanovich, 1975) and *Why Me? What Every Woman Should Know About Breast Cancer to Save Her Life* (Signet/NAL, 1977).

EDITOR'S NOTE: Mrs. Kushner has a background including pre-med, experimental psychology, and journalism. She has written and lectured extensively on breast cancer. She was the only lay person participating in the Consensus Development Conference on the Treatment of Primary Breast Cancer of the National Institutes of Health. She was the only voting woman. She had a modified radical mastectomy for cancer of the breast in June, 1974—a two-stage procedure with a diagnosis confirmed, at her insistence, by four independent pathologists. She has had a reconstructive mammoplasty in June, 1978.

Undoubtedly, there are even more ways to treat primary breast cancer – each procedure having a different name, depending on the number of lymph nodes taken from what level, as well as on which parts of the woman's anatomy are to be irradiated or treated in some other way. And then, of course, there are varying views on the efficacy of adjuvant therapy – either by hormones of some kind, antiestrogens or by potent drugs, used as single agents or in varying combinations. Small wonder that we women are thoroughly confused, especially when we are continually being told that the survival rates for all of these different procedures are "not statistically significant" from each other, no matter what was done.

Another reason this Consensus Development Conference is so important to us women is that all breast cancers appear to be treated by whatever procedure happens to be the preference of that particular surgeon – not by a specific therapy indicated by the specific type of breast cancer a woman has. It seems as if this disease were a ruptured appendix to be removed by the same kind of incision in the same place in every abdomen!

Again quoting from an American College of Surgeons' Report (This one, the "Final Report," issued 21 February, 1979), there were fourteen (14) different kinds of breast cancers found amoung the 23,777 tumors studied histologically for this survey. These were:

"In situ
Paget's
Lobular infiltrating
Ductal infiltrating
Papillary
Scirrhous
Medullary
Colloid
Comedocarcinoma
Inflammatory
Adenocarcinoma (not otherwise specified)
Carcinoma (not otherwise specified)
Other
>1 Histologic type"

Rather than repeat the information from this ACS report (Table 27), the surgical-accounting of how this wide variety of breast cancers was treated is reproduced on the following page.

As you can see, 52.44 per cent – more than half – of the women who had *in situ* carcinomas of some type were treated by more than a total mastectomy. This means, in absolute numbers, that about 242 women suffered from excessive surgery, more surgery than is considered necessary even by those who are thought to be "radical" in their treatment of invasive breast cancer.

The same table shows that 56.74 per cent of women with distant metastases present at the time of primary treatment – about 922 women – had some kind of mastectomy performed. Although removal of the breast is necessary if the gland is ulcerated, infected or when the tumor is exceedingly large, it is difficult to believe that such a large proportion of women with advanced disease at the time of initial surgery were in these categories.

To summarize, both of these tables raise more questions about the treatment of breast cancer, in women's minds, than they answer. Perhaps they are meaningful to surgeons, but to us, the numbers are puzzling.

For example:

As Table 27 shows clearly, all of the different breast cancers listed above—excepting *in situ* carcinomas—are grouped together according to the extent of the disease: localized, regional or distant. Nowhere in this exhaustive report has the ACS considered the types of breast cancer to be important enough to mention in terms of the different treatment modalities used. This, of course, raises the question as to whether the histological study was considered when the individual surgeons made their treatment decisions in the operating room.

The report gives no clues about this vital matter. There is no category giving the number of women (if any) whose definitive treatments – whatever they were – were based on their permanent-section diagnoses, rather than on frozen-sections. One can only infer that these surgeries were performed only on the basis of the frozen-sections' statements: "Malignant" or "Benign." What other reason could account for that 52.44 per cent who had more than total mastectomies for *in situ* breast cancer or for the 200 who had radicals?

As for the hundreds of mastectomies performed on women who had stage IV disease, such a high rate of mastectomies among women who already had metastatic disease at the time of surgery is, again, a signal that definitive treatment was probably done on the basis of the frozen-section pathology report. Surely, no surgeon would allow a woman to endure extensive surgery if it was already known that the disease had metastasized and that excising more tissue would do her lifespan no good. These women were probably not staged in advance.

Thus, this recent report of the American College of Surgeons illustrates my second point most graphically: Should all breast cancers be treated as if they were a single disease, regardless of their specific types and the degree to which they have already invaded other organs?

There is another issue that has not yet been address-

Table 27

DISTRIBUTION OF 24,136 CASES OF BREAST CANCER BY STAGE AND TYPE OF SURGERY (ALONE OR IN COMBINATION)

Type of Surgery Alone or in Combination	*In Situ*	*Localized*	*Regional*	*Distant*	*Stage Not Known*	*All Stages*
	N: 462	N: 11,845	N: 10,040	N: 1,626	N: 163	N: 24,136
None	2.2	1.6	3.5	42.9	14.3	5.2
Wedge excision	12.6	3.3	1.3	8.5	3.7	3.0
Total mastectomy	32.5	14.1	5.8	19.9	18.4	11.4
Total mastectomy with low axillary dissection	9.1	5.8	5.5	4.4	6.7	6.1
Modified radical	20.1	24.3	26.1	9.9	14.1	23.9
Radical (Halsted)	23.2	49.3	54.5	12.4	36.8	48.4
Radical mast. with internal mammary node biopsy	0.4	1.4	2.0	1.6	1.8	1.7
Super radical	0.0	0.2	0.2	0.4	1.2	0.3
All Surgeries	100.0	100.0	100.0	100.0	100.0	100.0

ed by a group such as this one. This problem is a direct result of the success of the various screening modalities now being used to detect early breast cancer.

We are constantly told that finding a breast cancer when it is microscopic and cannot be felt is a virtual guarantee of being cured. But it is difficult to convince a woman that she must lose a breast because of a spot that is barely visible on an X-ray. Radiologists and the manufacturers of mammography equipment have done an admirable job of reducing radiation exposure dosages, and women should no longer be afraid that an occasional low-dose mammogram will induce a breast cancer. But the exquisite sophistication and sensitivity of mammography has created a new fear: Will the X-ray or other early-detection technique find something that—if undiscovered—might never become life-threatening at all?

Physicians, surgeons and public as well as private agencies have taught us the early warning signs of breast cancer. The lay media have inundated us with this information in addition to the multiple primary treatments now being used – always, we are told, with the same, unchanging survival rates.

Somehow, this makes little sense to us. Why, after all, should we lose a breast because of an *in situ* cancer that is never going to invade its neighbors? And why should we be expected to take the time, trouble and spend the money to detect a miniscule cancer if it is to be treated with the same operation – amputation of the breast – as a tumor the size of a pea, an almond or an egg?

The very fact that this Consensus Development Conference has been convened and that all of you are here to examine this issue is convincing evidence that you – the experts – do not think the situation makes good sense either. It is up to you to decide on a logical and uniform method for treating this number-one killer of women. We are depending on you to do this, so that when we meet in lingerie departments, we will no longer compare notes (and scars and chest-wall defects) and wonder why Dr. X removed only the tumor in Mrs. Y's breast. Why do Drs. A, B and C insist on radical mastectomies for the same small lumps and thickenings?

The 1977 Consensus Development Conference on Breast Cancer Screening resulted in several recommendations, one of which is vital to resolving the question before this Conference as well. That Conference recommended that there be "concurrent pathological review" of all "minimal" breast cancers, so that any danger of misinterpreting the diagnoses would be eliminated entirely. (For the purpose of the mammography issue, the definition of "minimal" was an *in situ* lesion or one that was smaller than one centimeter.)

As a suggestion for resolving the problem regarding primary treatment of breast cancer – the matter now before this Conference – I would like to offer an amendment to this earlier statement: Unless the woman objects, or unless delaying definitive treatment is – for some serious medical reason – contraindicated, *no definitive primary treatment whatsoever* be performed solely on the basis of a frozen-section diagnosis.

Instead, I urge this Conference to repeat the recommendation of its predecessor that there always be concurrent pathological review of permanent sections of biopsy specimens. Then, and only then, can rational primary breast-cancer treatment be chosen for a particular woman, individual treatment that takes all known prognostic factors into account. There is already evidence that estrogen receptors and certain immunological and histological markers are discriminants that can help predict the course of the disease. None of these can be studied in the few minutes required for a frozen-section diagnosis.

When this has been done and several independent (i.e., not members of the staff of the same institution) agree that a radical mastectomy of some kind is indicated, then so be it. Most reasonable women would rather lose their breasts and their axillary nodes than their lives.

But reasonable women cannot accept unreasonable treatment, and this is the way breast-cancer surgery appears to be done today. The treatment we get depends on the person doing the treating – not on the tumor. We are counting on this Conference to abolish such arbitrary practices, once and for all.

Thank you.

A Patient's Point of View on Immediate Breast Reconstruction After Mastectomy

HELEN LILLIE

The first week in May, I went, as a journalist, to the White House Correspondents' Dinner in Washington wearing a dress held up by one narrow strap, with the other shoulder completely bare. I looked and felt good in this outfit—yet almost exactly two months before, I had undergone a modified radical mastectomy at Georgetown University Hospital. Immediately after my surgeon had removed a malignant tumor from my breast, I underwent a complete breast reconstruction, so that instead of emerging from the experience with a sense of loss and disfigurement, I had a better figure than before. All I lacked was a nipple, and that, I've been assured, I'll have implanted eventually.

Immediate reconstruction of the breast after a mastectomy is done in several medical centers in the USA. It was instigated at Georgetown in December, 1976, by Dr. William F. Feller, an oncology surgeon, and Dr. John W. Little III, a plastic surgeon. To date this dual team has performed between 30 and 40 immediate reconstructions, the majority of them extremely successful.

These two specialists tell patients, however, that they can't always do the reconstruction. During the first operation—the removal of the tumor—there may be contraindications, and if this is the case, the second operation is put off for several months.

Knowing this, it was greatly reassuring to me when I came around after the surgery to find that the reconstruction had been done. It meant my doctors felt I wasn't likely to have a recurrence of the cancer.

In mid-February, my left breast had become extremely tender and sore. I'd found a lump in it in 1969, but this had been checked out by a mammogram as

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HELEN LILLIE is a professional journalist who writes for medical journals.

benign so I hadn't paid much attention to the breast thereafter. However, the new soreness was in a different area—up close to the nipple—and when it didn't go away, I went to my GP. He immediately ordered a mammogram, and, when he saw the results, told me I must consult an oncology surgeon. He offered to find one for me, but I said I'd like to talk to my husband, who is a science writer and knows the local medical scene well.

I also went straight home and telephoned Rose Kushner's Breast Advisory Service. I had met Rose and also reviewed her book on "Breast Cancer" for a British medical newspaper, and I knew she had all the most up-to-date information on the subject at her fingertips. She told me that I could get myself into a clinical research program at the National Institutes of Health which, however, randomized patients and might result in my being treated by radiology rather than surgery. This didn't appeal to me, primarily because I like to feel I'm in control of the therapy given to me, and also because, from my own reading, I knew I was the typical cancer personality, i.e. moody and prone to holding grievances, and I felt I wanted my accumulated hostilities cut right out of me rather than simply reduced. This may not make sense to a doctor, but it does to me.

Both my husband and Rose Kushner suggested that I consult Dr. William F. Feller of Georgetown, which I did. His first step was to do a biopsy which he managed to work in on the same day that I initially met with him. He told me, as soon as he got the pathology report, that the tumor was malignant, and that, in a few days, I should come to his office and we would discuss what should be done about it. This boiled down to surgery or radiation and I opted for surgery. I don't know how long Dr. Feller talked with me at that stage, but I know I never felt rushed, and I was able to ask him a lot of frank questions—about the long term prognosis, what might come after the surgery, and how well established the immediate reconstruction procedure was. He answered all these questions, then asked me one: "Do you want to talk to another surgeon before you do anything?"

That, if nothing else, sold me on Dr. Feller. I did no more special reading other than a most informative pamphlet of Rose Kushner's, available through the National Cancer Institute, and called IF YOU'VE THOUGHT ABOUT BREAST CANCER.... It anticipated all the doubts I had. By a spooky coincidence, it had arrived at my house in the mail just two days before I saw Dr. Feller. As for Rose, she proved a strong bulwark of strength and information. She phoned me several times, sometimes in the evening, and the day I went into the hospital, and she gave me a lot of good, practical, female advice, such as what kind of nightgown to wear during my convalescence, all of it very useful and encouraging.

After I had decided on the surgery, I had bone and liver scans, and also talked with Dr. Little, the plastic surgeon. He examined my breast, and told me, as Dr. Feller had done, that he would do the reconstruction at the same time as the tumor removal only if the situation looked promising. He also warned me that I would have to spend extra time in the hospital if both operations were done simultaneously, but, as things turned out, I was there only ten days. I was discharged as soon as two drains were removed from my side. Although I was weak, and had a lot of swelling down my side and couldn't lift my arm very high, I felt well and was in good spirits. I had, incidentally, been in excellent health prior to the discovery of the tumor.

The full implication of why I felt so chipper didn't hit until I went to see the two surgeons four days after my discharge from the hospital or less than two weeks after the surgery. First I saw Dr. Feller, then Dr. Little, who proceeded to remove all the ace bandages that had covered my chest. He told me to go home and put on my regular bra! Since I'd gone to his office wearing a rather thin blouse under a suit, I was glad I'd thought to add a scarf, which concealed my nakedness!

I have since learned, from other women who have had mastectomies without immediate reconstruction, that there is great trauma attached to losing a breast. None of this did I experience. I had to spend some time, each day, massaging myself, and found this hard at first. However, when I realized that I was well held together and the prosthetic material was softening up, I grew bolder. I also went back, quickly, to a regular Yoga regime, adding new positions as soon as I felt I could manage them. This speeded up my arm's regaining its muscle tone, and helped to diminish the swelling around my waist.

I was well warned by both surgeons that immediate reconstruction was a recent procedure and therefore might complicate the situation should my cancer recur. Dr. Feller recommended a brief round of adjuvant chemotherapy, as preventive medicine.

Personally, I felt the risk was justified because I am over 50 and don't expect to live more than thirty more years at the outside, at least I hope I don't. I want to get as much mileage out of the time remaining to me as possible, and this means I didn't welcome the prospect of a second round of hospitalization with another general anesthetic and all its side effects. The toll on both my physical and nervous system would have been so great that I might well have hesitated to submit to another operation for purely cosmetic reasons. There are, frankly, few situations I find as traumatic as waiting around in doctors' offices and undergoing examinations, even if these are painless. This is a point of view I find few physicians appreciate.

So these were important factors in my opting for immediate reconstructive surgery. And I am well satisfied with the result, even though the job is still incomplete. The nipple will be added as an outpatient procedure.

Also, I was reinforced by the knowledge that I had been given good medical advice. My husband, as a medical writer, had double-checked everything told me. He went with me to see Dr. Feller when we discussed the results of the biopsy. He also boosted my shaky morale throughout, and tangibly demonstrated great love in taking over all the household duties, including the cooking, for well over a month after I came home from the hospital.

Rose Kushner, as a tower of strength and information I could never thank enough. It is encouraging that she has just been appointed to the National Cancer Advisory Board. I also found myself tuned in to an "old girl network" of former mastectomy patients, now recovered, whose experiences were frankly offered to me, by way of reassurance, sometimes by people I scarcely knew. While in the hospital, I was also visited by the Reach to Recovery volunteer, and though I didn't need her practical advice, I found it valuable to talk to her. The American Cancer Society also sent me notices of discussions on living with breast cancer which again I didn't avail myself of, but I was glad to know the information was there. The ministers of the Presbyterian Church I go to and the nuns at Georgetown University Hospital were so supportive that, together with the prayers, flowers, cards, and good wishes of many friends, I was able to maintain a positive attitude which I know contributed to my rapid recovery. I have had little subsequent depression, and I'm quite sure that a major reason is that I never had to cope with a sense of mutilation.

BOOK REVIEW

I Am Whole Again—The Case For Breast Reconstruction After Mastectomy. Jean Zalon with Jean Libman Block. Random House, New York, 1978, 151 pp., $7.95.

Ms. Zalon, who had a mastectomy in 1970 and reconstruction in 1974, is a woman on a crusade, telling others that after the nightmare of mastectomy there is the hope of reconstruction. She has written an intelligent, warm, and vastly informative book.

She tells of her own experiences and includes interviews with other mastectomy patients. She has before-and-after pictures of reconstruction. She discusses evenly and without hysteria the feeling of being different, the feeling of not being yourself.

She makes it very clear that there are steps which can be taken by the surgeon, i.e., nipple banking or incision technique which will ensure a better reconstruction. She also mentions that reconstructions have been done many years after mastectomy. She discusses the shape of the prosthesis, what can be done if the old and new breast do not match, but above all the gaining of a positive female self-image.

She writes of the feeling that so many mastectomy patients have that they *must be brave* and then relates the pattern of grief which must be lived through after any loss. She feels very strongly that everyone involved with these women must be informed of the real feelings that occur and must make a commitment to help in a positive way. She says that, in the past, too many medical people have not understood the horror of mastectomy that women have. Too often, tears of grief were met with a "Why are you so upset; we cured your cancer" attitude.

Ms. Zalon poses questions and answers them. How soon after mastectomy to reconstruction? How much will it cost? She lays to rest many of the more common worries. She says that reconstruction is not for everyone, some because of radical surgery; but for those who want it, she has written a book with a lot of sensible guidelines. She wants every woman to know that mastectomy is not necessarily the final step.

This book is a consumer's guide but it is not a feminist diatribe. She thinks highly of most of the doctors she met. There are no tales of male chauvinist physicians or botched operations. The whole tone is reassuring. This is a well thought out book by a woman who has been through this particular horror and sees that her final solution may just be the answer for a lot of other women. It would calm many fears and may save some lives. This is a very important book and is highly recommended.

—Susannah English Curi, Goshen, CT

No Longer Immune

D. JOHN PECORINO, L.L.B.

Initially I would like to give you a brief history of the changing attitude of the courts toward hospitals and their personnel. Then I would like to touch on the standard of care that health care providers owe their patients, some of the things I would do if I were a health care provider, and finally, what we all should be doing.

At one time, if a hospital was founded and intended for use of the public and was engaged in the free assistance of the poor, the suffering or the distressed, it was protected by charitable immunity. I will show how immunity was established—how it gradually eroded—and how this change poses a challenge to all of us.

Tort Liability of Charitable Hospitals to Patients

In 1876 the Supreme Court of Massachusetts in the case of **McDonald vs Mass General Hospital**[1] initially announced the rule in the United States that a charitable hospital is not liable for injuries caused by the negligence of its agents and employees.

This was the law until the case of Glavin vs Rhode Island Hospital three years later, which held that a charitable hospital was liable for injuries caused by the negligence of an intern. However, shortly thereafter the Rhode Island legislature enacted a statute granting immunity and thereby repudiated the Glavin decision. The immunity doctrine continued until 1920 when the Minnesota courts held charitable hospitals to be fully liable for the torts of their employees and agents.

New Hampshire followed in 1939, North Dakota in 1946, Vermont in 1950, and Delaware in 1951. The fifties saw the courts abrogating the rule of charitable immunity and it began disappearing, in the absence of legislative action to the contrary. Most courts took the position that it was the responsibility of the legislature to establish laws regarding charitable immunity.

In our own State of Connecticut, the doctrine of charitable immunity was firmly established in the law by the case of **Hearns vs Waterbury Hospital, 1895.**[2] It was reaffirmed in 1944 by the cases of Tocchetti vs Johnson Memorial Hospital[3] and Edwards vs Grace Hospital Society.[4] The only exception to this immunity occurred when there was corporate negligence on the part of a charitable defendant. Corporate neglect must necessarily mean neglect of the officers or managing directors who constitute the governing board of the corporation, as distinguished from the negligence of its ordinary employees—i.e., superintendent, physicians and nurses.

However, in October, 1967 the corporate neglect theory (charitable immunity) was abolished in Connecticut by enactment of Public Act. No. 52 (Sec. 52-557 D).

Things were apparently rather quiet nationwide until 1964 when the famous case of Darling vs Charleston Community Hospital[5] in Illinois erupted. At that time it was a landmark case because it illustrated the trend to impose greater responsibility on the hospital to insure the delivery of proper health care to the patient in the hospital. In this case a general practitioner treated a fractured leg in the hospital by closed reduction and cast. While in the hospital the patient continued to complain of pain in the leg until finally an odor about the cast was noted. The patient was ultimately transferred to a larger hospital where an orthopedic surgeon amputated the leg because of gangrene. Suit was brought against the general practitioner and the first hospital. The general practitioner's carrier settled his portion of the case for $40,000. The case against the hospital went to a jury and resulted in a verdict in the amount of $150,000. The hospital was permitted a setoff for the $40,000 and therefore was responsible for the difference of $110,000. The court held the hospital liable for the delivery of adequate patient care including supervision and control as would assure same.

The seventies followed by the courts expanding the responsibility of the hospital and its governing body.

Let's take a look at some of these cases:

Penn Tanker Co. vs. United States (1970)[6]—A seaman received an eye injury in a welding accident. An ophthalmologist at the U.S. Public Health Service Hospital operated on the seaman in a negligent man-

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This paper was presented at a clinical symposium at the Villa Capri, Wallingford, CT, March 20, 1980.

ner. As a result the seaman lost the sight in the eye—became depressed, and subsequently killed himself.

It was known to the administrator of the hospital that the ophthalmologist was an alcoholic and not doing well in his therapy program. The court found that the United States, through the administrator of the hospital, was negligent in permitting the doctor to operate on the seaman's eye and in permitting the doctor to attend, treat and diagnose the seaman's condition. It was also found that the hospital was negligent in failing to enforce a proper and recognized medical procedure at all material times during the operation, thereby breaching the standards of hospital accreditation of the Joint Commission on Accreditation of Hospitals.

Next case is **Joiner vs. Mitchell County Hospital Authority (1971).**[7] The Georgia Court of Appeals held that a hospital is liable for the injuries sustained by a patient due to the ministrations of an unskilled staff physician if the hospital negligently failed to exercise care in determining his professional competence prior to granting a staff appointment.

This was followed by **Purcell vs. Zimbleman (1972).** The treating physician in this case performed the wrong kind of surgery for the type of condition the patient had. The evidence showed that he had made similar mistakes previously and that he had been involved in a number of malpractice suits.

The patient contended that the hospital had a duty to the public to allow use of its facilities only by staff physicians who were professionally competent and who treated their patients in accordance with established medical practices. The patient said the hospital breached its duty in failing to take action against the surgeon when it knew, or should have known, that he lacked the skill to treat the patient's condition.

The hospital contended that it was not liable for the surgeon's malpractice because he was an independent contractor and there was no reason to expect a specific act of malpractice.

The court said that the department of surgery was acting for and on behalf of the hospital and that if it was negligent in not taking action against the surgeon or recommending to the board that the action be taken, then the hospital would also be negligent. The court said it was a jury question as to whether or not the hospital was negligent. The judge submitted the case to a jury and the jury found against the surgeon and the hospital.

Our next case is the well-known case of **Corleto vs. Shore Memorial Hospital, NJ (1975).**[8] A medical malpractice suit was brought against a physician who performed abdominal surgery on the patient. Suit was also made against the hospital, the administrator, board of directors, and medical staff. These defendants moved to dismiss the complaint against them for failure to state a claim on which relief could be granted. The superior court denied the motion. It was held the hospital had a duty to a patient not to permit an incompetent doctor to perform surgery and to remove a staff member from a case which had gone beyond his control and competence. Failure to perform this duty would be a basis on which liability could be imposed on the hospital. It further held the medical staff was amenable to suit under New Jersey law as an unincorporated association.

The Corleto case is an example of the theory of corporate negligence being carried to the extreme—in fact, the naming of all staff doctors as defendants was a new dimension. It is probable that many of the staff physicians never knew or heard of the surgeon who performed the abdominal surgery.

What are these cases telling us?

1. Physicians must not be permitted to violate rules established by the medical staff. *(Penn Tanker Co. vs U.S.—Texas 1970)*[6]
2. The hospital through its board of directors must formulate and enforce rules to ensure patient safety. *(Tonsic vs Wagner—Pa)*[9]
3. The hospital must supervise the selection and activities of staff physicians *(Mitchell County Hospital Authority vs Joiner—Ga)*[7]
4. The implications are that the hospital, through its governing board, has a duty to investigate and review the competence of physicians who use its facilities. This includes the duty to use reasonable care in the granting of staff privileges, and a duty to terminate or limit staff privileges once the incompetence or impairment of a physician has become known. *(Tucson General Hospital vs Zimbleman—Ariz)*[10]

The only practical method availabe to a governing board for determining competence is to rely upon a credentials committee or a peer group review committee of the medical staff. This is probably why the Joint Commission on the Accreditation of Hospitals (JCAH) and state law requirements, in fact or effect, make medical staff committees the agents of the governing board when reviewing the quality of the physician's work. Liability will probably be imposed, if at all, on the basis of some act, or failure to act, by the individual(s) involved.

Agents of a corporation are personally liable if they fail to carry out or negligently carry out a duty owed to an injured party. The committee members involved are in the most vulnerable position.

If there is evidence that the treating physician was known to be, or should have been known to be incompetent, such evidence would be most damaging against the physician or physicians who had the initial opportunity and responsibility to make that determination. They would have the best opportunity to obtain knowledge of professional fitness.

Obviously, each link along the chain of responsibility, i.e., committee to full medical staff, to governing body, reduces the degree of personal involvement and thereby makes the possibility of personal liability more remote. Unfortunately, the courts may tend to find new or expanded theories to impose corporate liability on the governing bodies. That is the lesson learned from the previously cited cases. But remember the root cause of such liability is negligence by one or more people in the process of evaluation.

I would like to stress that courts are expanding the potential liability of committee members, staff members, and members of governing boards. We must realize that significant potential liability does exist. The degree of risk is proportioned to the degree of negligence on the part of the individual committee members.

To protect the interests of the members of the committee responsible for evaluation of qualification for practice, and the related responsibility on the hospital, the following practices should be followed:

1. Investigate thoroughly.
2. Be sure of effective communication.
3. Insist that the decisions of the committee and the facts upon which those decisions are based are recorded.
4. Be sure that the objection is made a matter of record in those instances where the physician disagrees with the decision of the committee.
5. Treat these matters with the care their potential damage warrants.

And, finally, it is important to realize that the courts are continuing to broaden the concept of a hospital's duty to insure that its staff members are professionally competent within their special field of practice to provide quality health care to the hospital's patients.

Webster's definition of malpractice is:

1. A dereliction from professional duty or failure of professional skill or learning that results in injury, loss or damage;
2. An injurious, negligent, or improper practice.

As health care providers you will be judged by that degree of care, skill and learning expected of a reasonably prudent health care provider in the profession or class to which you belong, acting in the same or similar circumstances within the State of Connecticut. Moreover, a specialist will be held to the standard of care of a similar specialist rather than that of a physician in general practice.

Reasons for Claims

There are various reasons for malpractice claims. Some are:

1. As medical technology continues to become increasingly sophisticated, the risks involved also increase.
2. The general public often has unrealistic expectations as to what medical science can do.
3. The health care delivery system has become increasingly impersonal.
4. There is a greater tendency on the part of patients to resort to the courts with their grievances.
5. There is a greater willingness on the part of courts to grant high awards.
6. Legal defenses have eroded.
7. The high rate of inflation increases the dollar amount of loss sustained by injured patients.

And how has the medical profession reacted?

1. By practicing defensive medicine
2. Seeking legislation
3. Instituting countersuits
4. Requesting arbitration
5. By seeking screening panels
6. Injury compensation fund
7. Exploring no fault insurance
8. Educational programs

Obviously, while a good deal of time and education has been expended in these areas, unfortunately it has not solved the problem. Frankly, I don't know if we will ever solve all of the problems, but I would like to make a few suggestions regarding what I would do if I were a health care provider from what I have learned over the years in working with physicians, nurses and hospitals.

1. Put my patients at ease—establish rapport.
   Many people are genuinely afraid of visiting a doctor's office and/or a hospital, especially if it has anything to do with the possibility of an operation. You have an obligation to put these people at ease, to give them a feeling of confidence and assurance. By simply developing a pleasant "bedside" or "chairside" manner with your patient you can accomplish this. Those extra few minutes you spend with your patient can make a big difference. And, remember—whatever you do, never become antagonistic.
2. Maintain accurate records.
   Every physician, nurse and health care provider should maintain accurate records. The absence of X-ray reports, lab reports, consent forms, etc. makes a case more difficult to defend, even when you are right. Remember that your records are witnesses that never die. Accurate records help make you right.
3. Exercise good reason.
   Exercising good reason, good judgment and professional skill are your strongest allies against malpractice incidents. Remember that your best judgment should always prevail.
4. Obtain an informed consent.
   The patient has a right to know. Be sure the patient is listening.
5. Never guarantee a cure.
   No physician can guarantee the outcome of any operation or recommended treatment. So don't.

Good charting is essential to your protection. Good charting takes time, but it's well worth the effort. It contributes to better patient care, and it can help you avoid many traumatic hours in a courtroom. Good charting protects you and your hospital.

A recent trial graphically demonstrated the benefits of good charting. A teenager, brought to a hospital emergency department following an auto accident, complained of shoulder and head pain. She was examined and treated, then released with a "head sheet" and verbal instructions to her family to watch for signs of possible head injury. Despite obvious signs and symptoms of head injury, the patient was not returned to the emergency department until the next day. All efforts were made to save her, but she died a few days later.

Suit was brought against the hospital, alleging failure to provide literature concerning head injury symptoms and precautions or to adequately inform of the dangers after a blow to the head.

Because of good charting there was a written record of "head sheet" presentation and verbal instructions to the patient's family. This evidence convinced the jury to accept the testimony of hospital personnel. Inadequate charting can be costly.

Another case dramatically highlighted the consequences of inadequate charting:

At 1:00 a.m. a nurse phoned the attending physician about a patient's situation and received a medication order. While no order for frequency of observations was specified, the PDR (Physician's Desk Reference) clearly stated that the patient should be closely supervised after a large initial dose of such medication. The patient was discovered dead at 6:30 a.m. During the subsequent trial, the hospital contended that there had been patient-checks every twenty minutes for the first two hours following medication, and hourly thereafter. But the lack of any entries in the chart concerning times of checks or observations of the patient's reactions and changes made it impossible to refute the claim of inadequate care.

Remember that care not recorded may be considered care not done. Always follow the procedures and guidelines for charting. Time spent on clear, complete and accurate charting can protect you as well as your patients.

And, finally, involvement—what can we all do?

The medical and hospital profession must accept a greater responsibility for controls from within. The very nature of medical practice and hospital operation is such that outside lay interests are generally not in a position to ferret out incompetence and inefficiencies which can lead to avoidable poor results. The medical profession should establish criteria of acceptable practice and establish means of control whereby these criteria are always met. There should be a closer relationship between medical and hospital interests whereby the abilities of both are utilized to guarantee the most efficient operation possible in our hospitals, using all trained manpower in the most productive manner possible.

The legal profession and our judicial system should carefully analyze their contribution to the present malpractice problem. They should recognize what is just. They should also establish control from within whereby none of their members would be allowed to follow a course which produces unjust verdicts against those striving to provide our country with the best possible care.

The general public—There must be some means of educating the general public to a proper understanding of what they should expect and have a right to expect from all interests involved in providing medical care. They must be apprised of what realistic costs are involved to provide the standard of care. They must learn what the reasonable recompense is when there is a case of real negligence and not to expect that the patient will receive more. They must be given a thorough understanding of present-day capabilities with the available facilities and manpower. They cannot expect more than is available.

The insurance industry must develop a uniform industry system for the collection of claims and related (rate) information. This information must be readily available for dissemination to the proper people for study and necessary action. The insurance carriers must work very closely with the medical and hospital societies and have a viable loss control and education program.

I think we all have to take a long, hard look at ourselves, stop blaming each other, and plan and work together.

Rarely are the achievements of quality or greatness arrived at by accident. More often, the achievement is by design, by deliberate plan, and by persistent hard work. Thus, we all have to work together, and with deliberation, planning and by persistent hard work we will achieve our goal.

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Factors Responsible for Increasing Cost of Medical Care

AMA BOARD OF TRUSTEES

At the 1978 Annual Convention the House of Delegates referred a resolution to the Board of Trustees. The resolution calls for an outline of the factors contributing to the cost of medical care which can be used in reviewing proposals to modify medical care reimbursement and proposals which may affect the quality and accessibility of health care.

The following study, and an outline based on the study, was prepared by the AMA's Center for Health Services Research and Development. It examines the trends in health care expenditures during the past quarter century and identifies the principal factors which lie behind these trends. Since aggregate cost data do not exist, regularly reported data on aggregate health care expenditures are used to measure the costs of care.

Health Expenditures: Recent Trends

Health care expenditures have risen rapidly since 1950, both in absolute terms and as a share of GNP. Total health care expenditures have risen from $12.0 billion in 1950 to $139.3 billion in 1976, an increase of more than 1,000 percent.In 1950, health care expenditures accounted for 4.5 percent of GNP; by 1976, the figure had risen to 8.6 percent of GNP, and it is still growing. Expenditures for personal health care show a similar percentage growth. Trends in national health expenditures are summarized in Table l. The government publishes two measures of aggregate expenditures for health care services: total (which includes all health care services and supplies) and personal (which consists of total expenditures less prepayment, administration costs, research costs, construction costs, and costs of government public health activities).

Components of Increased Personal Health Care Expenditures

Increases in medical care prices, a growing population, and increases in the quantity and quality of care consumed have each played a role in the growth of personal health care expenditures. Table 2 presents the dollar and percentage impact of each of these three factors from 1950 to 1976. Figures for interim periods are also presented to illustrate changes in the impacts of the three components within the 26-year period.

Medical Care Prices: The increase in medical care prices accounts for nearly 55 percent of the total increase in personal health care expenditures from 1950 to 1976. With the exception of the wage and price control years, 1971-1974, medical care price increases have been the largest factor in the growth in health care expenditures. For the period as a whole, medical care prices rose 244 percent as measured by the medical care index within the Consumer Price Index (CPI). The overall CPI rose 136 percent; thus, while medical care prices rose faster than the CPI, *a significant portion of medical care price increases is attributable to general inflation. This general inflation, in turn, is due in large part to the government's taxing, spending, and monetary policies.*

Because quality adjustments are made for certain indices within the CPI, but not for health care, the computed price increases overstate the true price increases. Further, as seen in Table 3, there were dramatic differences among the components which are included in the medical care price index during this period. Thus, factors affecting overall medical care price increases may not be relevant for all of the health care marketplace.

Population Increases: Only 10.5 percent of the increase in total expenditures on personal health care during the period 1950-1976 can be attributed to population growth. The population increased 41 percent during this period, with the most rapid growth

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EDITOR'S NOTE: This report by the Board of Trustees was adopted by the AMA House of Delegates at its Annual Meeting in July, 1979.

Table 1

TRENDS IN NATIONAL HEALTH EXPENDITURES FOR SELECTED FISCAL YEARS
(in billions of dollars)

			Expenditures for Personal Health Care [a]				
Year	*All Health Expenditures*	*Percent of GNP*	*Total*	*Private*	*Public*	*Federal Portion of Public*	*Medicare and Medicaid Portion of Federal*
1950	12.0	4.5	10.4	8.3	2.1	1.0	N.A.[b]
1960	25.9	5.2	22.7	17.8	4.9	2.1	N.A.
1965	38.9	5.9	33.5	26.5	7.0	2.8	N.A.
1970	69.2	7.2	60.1	39.6	20.5	13.4	9.4
1975	122.2	8.4	105.7	63.8	42.0	28.9	21.2
1976	139.3	8.6	120.4	72.0	48.4	33.7	25.2

[a] Includes expenditures for health services and supplies less those for prepayment, administration, research, construction, and government public health activities.

[b] N.A. Not applicable since program started making payments in 1966.

Source: Congressional Budget Office, Background Paper, "Expenditures for Health Care: Federal Programs and Their Effects," U.S. Government Printing Office, Washington, D.C., August 1977.

Table 2

FACTORS CONTRIBUTING TO THE INCREASE IN PERSONAL HEALTH EXPENDITURES:
SELECTED PERIODS, FISCAL YEARS 1950-1976
(in billions of dollars)

Source of Increase	*1950-65*	*1965-71*	*1971-74*	*1974-76*	*1950-76*
Price	10.1	16.8	10.4	22.4	60.1
Population	4.9	3.0	1.9	1.7	11.5
Quantity and Quality Increase	8.1	13.9	11.8	4.6	38.5
Total	23.1	33.7	24.1	29.1	110.0
			Percentage Distribution		
Price	43.8	49.9	43.1	78.3	54.6
Population	21.0	8.9	7.9	5.8	10.5
Quantity and Quality Increase	35.2	41.2	49.0	15.9	34.9
Total	100.0	100.0	100.0	100.0	100.0

Source: Congressional Budget Office, Background Paper, "Expenditures for Health Care: Federal Programs and Their Effects," U.S. Government Printing Office, Washington, D.C., August 1977.

occurring in the first decade. An implication of the large increases in health care expenditures, combined with the slow growth of population, is that the expenditures per capita grew dramatically (specifically, 715 percent; Table 3).

Quantity and Quality of Care: Nearly 35 percent of the total increase in personal health care expenditures is attributable to growth in the quanity (per capita) and quality of health care services consumed. Both of these factors are difficult to measure precisely. That quantity has increased is seen in increased hospital admissions, outpatient visits, and physician visits per person. Per capital intensity of use, a measure of quality, has also increased. Availability and accessibility of facilities, have both improved.

Demand for and Supply of Health Care Services

Changes in prices and quantities of health care services can be explained, in part, by the large shifts in the demand for and supply of health care services which took place during this 26-year period.

Increased Demand for Health Care Services

Several factors can be identified as causing increased demand for health care services. Of these, three of the most important are increases in personal income, expanded insurance coverage of health ser-

Table 3

SUMMARY OF GROWTH FOR SELECTED YEARS

Category	*Year 1950*	*Year 1976*	*Percentage Change*
Prices [a]			
All Items	72.1	170.5	136
Medical Care	53.7	184.7	244
Prescription Drugs	92.6	115.2	24
Physicians	55.2	188.5	241
Dentists	63.9	172.2	169
Semi-Private Room	30.3	268.6	786
Population [b]	151.9	214.6	41
Personal Health Care Expenditures [c]	67.8	551.5	715

[a] Prices are consumer price indexes with 1967 = 100.

[b] Population is in millions.

[c] Expenditures are in current dollars per capita.

Source: Robert Gibson and Marjorie Mueller, "National Health Expenditures, Fiscal Year 1976," *Social Security Bulletin,* April 1977, Vol. 40, No. 4, pp. 3-22.

vices (including that provided by Medicare and Medicaid), and growth in the proportion of the population over 65. While researchers have been unable to determine the precise effect on the demand for health care services of any one of the factors, it is agreed that growing incomes and expanded insurance coverage are the most important.

Income: As consumers' incomes rise, all else equal, they increase their expenditures on health care services. Even though the exact relationship between personal income and health care expenditures is not known, it is known that the two move in the same direction. Government sources indicate that income rose more than 70 percent from 1950 to 1976; accordingly, the contribution of income increases on health care expenditures likely was substantial.

Insurance Coverage: Third-party payment mechanisms reduce the direct payment made by the patient at the time of care, which leaves the consumer less cost conscious when determining the quantity and quality of care he wishes to consume. If the consumer is less cost conscious, he will demand both a greater quantity and higher quality care, both of which increase total health care expenditures. Furthermore, this effect will continue to increase total health care expenditures as consumers' coverage by third parties increases. According to the Social Security Administration, the proportion of personal health care expenditures paid by third parties, including government, rose from 32 percent in 1950 to 68 percent in 1976. In addition, coverage is greatest for hospital care, where over 90 percent of all expenses were paid by third parties in 1976. This extensive coverage makes resistance to hospitalization very low and has contributed to the growth of hospital care within the health sector. Since hospital care is high-priced relative to ambulatory care, health care costs have risen accordingly.

The government has increased the demand for health care services by the introduction of Medicare and Medicaid programs and certain tax policies. The introduction of Medicare and Medicaid increased the availability of health care services to many poor and elderly. As seen in Table 1, Medicare and Medicaid expenditures have increased from $9.4 billion in 1970 to $25.2 billion in 1976. Total government expenditures have increased dramatically from $20.5 billion in 1970 to $48.4 billion in 1976. This $27.9 billion increase in government expenditures does not represent a net addition to total health care expenditures since some government expenditures on health care services replace expenditures that would have been made by the private sector. In addition, tax policies that do not treat insurance premiums as taxable personal income have increased employers', employees', and unions' incentives for both greater depth of coverage to the individual and coverage for more individuals.

Age Distribution: The third principal factor increasing demand for health care services is the dramatic growth in the proportion of the population age 65-or-above that has occurred since 1950. This growth has led to increased total health care expenditures since health service utilization and expenditures are much greater for the typical age 65-and-over person. Specifically, per capita expenditures on personal health care by those 65-and-over are 3.5 times per capita expenditures by those less than 65.

Increased Supply of Health Care Services

The supply of health care services has increased in response to the increased demand. As seen in Table 4, there has been substantial growth in the number of hospital beds, hospital employees, physicians, and all health professionals. Furthermore, there has been a dramatic change in the types of services available to patients. The past quarter century has witnessed the development and widespread adoption of intensive care units, cardiac care units, CAT scanners, and a host of others—all with important implications for both the cost and quality of care.

Economic theory predicts that increases in supply will lead to a decline in unit (per service) prices, other things being equal. However, in health care, especially in the hospital sector, increased supply may lead to an increase in unit prices; this phenomenon is closely tied to the cost-based reimbursement system. Furthermore, increased supplies of hospital beds and physicians (per capita) have been shown to lead to increased per capita utilization of health care services. Accordingly, the increased health care expenditures are attributable, in part, to the increased supplies of health resources.

The supply of health care services has been increased by the government's provision of funds for both hospital construction and medical education. From 1948 to 1971 the Hill-Burton Act provided 30 percent of total hospital construction funds and certainly contributed to the growth of hospital beds per capita seen in Table 4. An additional aid to hospital construction has been the ability of most hospitals to issue tax-exempt construction bonds. The Health Professions Educational Assistance Act of 1963 provided funds for construction and renovation of health professions schools and provided direct aid to students. This program contributed to the increased number of physicians and other health professionals seen in Table 4.

Table 4

TRENDS IN FOUR MEASURES OF THE SUPPLY OF MEDICAL SERVICES

Year	*Beds* [a]	*Employees per Daily Census*	*Physicians* [a,b]	*All Health Professionals* [a,c]
1950	330	1.78	—	—
1960	350	2.26	260	1,011
1965	380	2.46	289	1,168
1970	410	2.92	323	1,329
1975	440	3.39	375	1,575

[a] Number per 100,000 population.

[b] Includes medical doctors and doctors of osteopathy.

[c] Includes physicians, dentists, registered nurses, optometrists, podiatrists, pharmacists, and veterinarians.

Source: Congressional Budget Office, Background Paper, "Expenditures for Health Care: Federal Programs and Their Effects," U.S. Government Printing Office, Washington, D.C., August 1977.

In addition, some economists have charged that providers are capable of generating demand for their own services thereby offsetting the negative impact on fees of an increase in supply. However, to date no one has been able to show rigorously that such "supplier-induced" demand exists.

Technological Change

The development and diffusion of new technologies has led to increased cost of health care services. Most new technologies appear to have raised cost by using more manpower and more expensive equipment; they have, therefore, led to increased resource use. The impact of the diffusion of existing technology is seen in the increased use of laboratory tests per hospital admission of 8 percent annually from 1970 to 1976 and in the increased proportion of 300-bed hospitals with intensive care units from 21 percent in 1958 to 100 percent in 1975.

While some innovations have lowered costs, attempts to improve the quality of care have generally led to the adoption of cost-increasing technologies. Patients accept cost-increasing technologies, in part, because of extensive insurance coverage. Cost-based reimbursement has certainly played a role in the adoption of expensive, hospital-based technologies. Although the precise total impact of new technologies on costs is unknown, research to date indicates that it generally increases costs.

Other Sources of Rising Costs

In addition to those discussed above, a number of other factors have contributed to rising costs of health care services. Among the most important are growing regulation of the health care industry, increased professional liability insurance premiums and rising business expenses.

Regulation of the Health Industry: Growing regulation of the providers of health care services has contributed to the increased cost of providing care. All segments of the health care delivery system incur regulatory costs with the hospital sector affected the most. While reliable estimates of the costs to the health care industry as a whole do not exist, there is a growing body of evidence that the costs of regulation to society are substantial. Studies have measured the costs to hospitals of specific regulations, but the small sample size employed and the nonrandom selection of the hospitals used make generalizations difficult. In addition, these studies report total cost of regulation, not the increment to cost as a result of increased regulation that occurred in the past 25 years.

To obtain sound estimates of the cost of regulation to the health care industry, the President has established the Regulatory Analysis Review Group to study 10 to 20 specific regulations per year. In addition, a Presidential Commission on Regulatory Budgeting and Balancing, the Executive Branch's Regulatory Council, and the Department of Commerce have laid the foundation for detailed research into the total impact of federal regulation. These agencies have had to deal with both theoretical and data-related problems in their early stages—problems which have hampered prior efforts to obtain cost estimates. However, it is anticipated that reliable estimates of the costs of regulation will be available in the next few years.

Liability Insurance: Increased liability insurance expenses have led to increased physician fees and hospital charges. The trend toward more generous malpractice settlements by the courts has increased insurance premiums 600 percent for physicians and 907 percent for surgeons from 1960 to 1972. To avoid malpractice claims, many physicians and hospitals have practiced defensive medicine by increasing their use of laboratory tests, x-rays, etc. Defensive medicine, a secondary effect of increased malpractice settlements, has significantly increased health care costs.

Business Expenses: As seen above, nearly 55 percent of the increased expenditures for health care, 1950-1976, is attributable to the rising prices of health care services. Rising prices of health care services reflect, in part, the rising costs of producing those services. AMA figures indicate that from 1970 to 1976, physician expenses rose 75 percent, compared to a 54 percent increase in physician net income. However, since physician expenses represent a small (10.3) percent of total health care expenditures, the overall impact of these expenses on medical care prices is likely to be small. Turning to hospitals, Harvard economist Martin Feldstein has argued that from 1955 to 1975 the cost per patient per day increased 555 percent or 9.4 percent per year. Of this increase, 47.8 percent is attributable to increased nonlabor costs, 36.7 percent to increased wages per hospital employee, and 15.2 percent to increased employees per patient day. In the cases of both physicians' practices and hospitals, rising input prices reflect, in part, rising prices in the entire economy. In addition, expenses for both physicians' practices and hospitals have increased as a direct result of costs associated with governmental regulatory requirements and the third-party payment mechanism.

Conclusion

This report has examined the growth of health care costs during the period 1950 to 1976. Medical care costs were measured in terms of total expenditures on health care. It was shown that the growth in expenditures can be broken down into increases in medical care prices, a growing population, and increases in the quantity and quality of care consumed. Rising medical care prices is the most significant component, and a portion of it is attributable to general price level changes.

Underlying the growth in prices, quantities consumed, and quality are changes in the demand for health care, the supply of health care, and the development of new medical technologies. Increased third-party coverage for health care services, government subsidies and tax policies, and growing real incomes played an important role in all of these areas. It is evident that a significant number of the factors responsible for rising costs of health care are outside the influence of health care providers. For example, general price level changes, population growth, real income growth, and government subsidies and tax policies will continue to impact on the cost of health care irrespective of the actions of the providers of care.

Outline of Factors Responsible for Increasing Cost of Medical Care

I. OVERVIEW: Because of data limitations, the costs of health care are measured by expenditures on health care services. Increases in the costs of health care can be broken down into increases in the prices of medical care services; increases in the quantity and quality of care consumed per person; and increases in the size of the population.
  A. *Medical Care Prices*
    1. General Price Level (all goods and services)
    2. Prices of Specific Health Services
      a) Physicians' services prices
      b) Hospital charges
      c) Prescription drugs prices
      d) Dentists' services prices
      e) Other
  B. *Population*
  C. *Quantity and Quality*
    1. Proportion of Population Using Services
    2. Intensity of Service Use Per Capita
    3. Quality of Services

II. CAUSES: A portion of increased expenditures for health care services is attributable to an increase in the general price level, which, in turn, is attributable, in part, to the government's spending, taxing, and monetary policies. The remaining increased expenditures can be linked to rising real medical care prices and larger quantities and improved quality of health care services consumed. These changes are attributable to changes in the demand for and supply of health care services.
  A. *Demand for Health Care Services:* Factors which influence the quantity and quality of health care services that individuals are willing to buy. Key factors are income and health insurance coverage, including Medicare and Medicaid.
    1. Income
      a) Total per capita
      b) Distribution
    2. Insurance
      a) Number of individuals covered
      b) Depth of coverage
        (1) hospital services
        (2) surgical services
        (3) outpatient services
        (4) major medical
        (5) prescription drug
        (6) dental services
        (7) all other
      c) Extent of consumer cost sharing
      d) Method of reimbursement
    3. Population
      a) Total population
      b) Proportion over 65
  B. *Supply of Health Care Services:* Factors which influence the quantity and quality of health care services that providers produce. Key factors are the quantity of health manpower and facilities, as well as variables which affect the cost of producing services, including

labor costs and the costs of complying with government regulations.

1. Quantity of Resources
    a) Hospital resources per capita
    b) Office-based patient care physicians per capita
    c) Other health employees and resources per capita
2. Geographic Distribution
3. Technology
    a) Quantity of new technologies
        (1) equipment
        (2) procedures
    b) Availability of new technologies
        (1) geographic distribution
        (2) utilization rate
    c) Type of technology
        (1) cost increasing
        (2) cost saving
4. Regulation
    a) Impact on innovation
    b) Impact on acquisition
    c) Cost of compliance
        (1) money cost (direct)
        (2) time cost (indirect
5. Liability Insurance
    a) Direct cost
    b) Indirect cost of defensive medicine
6. Business Expenses
    a) Office practices
        (1) labor costs
            (a) costs per employee
            (b) employees per patient
        (2) nonlabor costs
    b) Hospital
        (1) labor costs
            (a) costs per employee
            (b) employees per patient
        (2) nonlabor costs

Health Care Expenditures

Over the past decade, the rapid increase in national health care expenditures had been cause for a great deal of concern, fueling the demand for cost containment legislation and shaping proposals for national health insurance. A special focus has been the increasing proportion of the Gross National Product (GNP) devoted to health care. This fraction in the U.S. was 5.3 percent in 1960, 7.2 percent in 1970 and reached 9 percent in 1979. There are many reasons for this increase, including aging of the population, increased public financing and advancement of biomedical knowledge.

To provide some perspective on this matter, the Social Security Administration recently completed a study comparing these figures for the United States with those of other advanced industrial countries. The results, which are summarized in the table below, show the U.S. occupying a middle position.

The full report is available in *Social Security Bulletin 43* (1980) 3-8.

	Health Care Expenditures as Percent of GNP	
Country	*1960*	*1975*
Federal Republic of Germany	4.4	9.7
Sweden	3.5	8.7
Netherlands	—	8.6
United States	5.3	8.4
France	5.0	8.1
Canada	5.6	7.1
Australia	5.0	7.0
Finland	4.2	6.8
United Kingdom	3.8	5.6

Month in Washington

National Health Insurance sparks keep flickering. The Senate Finance Committee has budgeted six days of sessions this summer on the issue.

Committee Chairman Russell Long (D-LA) steered the panel close to a vote recently but then postponed consideration after resistance surfaced on the budget-breaking aspects of any NHI plan.

The bill before the Committee has been chopped back in an effort to make it easier to win approval. The catastrophic provision was changed to a voluntary plan with tax incentives to encourage businesses to purchase such coverage for their workers.

Several Senators have remarked privately they believe the NHI bill is dead, but when the powerful Long is running the show and wants a bill, legislation can't be written off.

The legislative trip through committee, Senate floor, House committees and House floor, appears far too lengthy and difficult for a NHI bill to survive this year, particularly in the light of the growing fight for a balanced budget.

The House-Senate Conference Agreement on Congressional Spending Limitations has directed a $1.4 billion reduction in Medicare-Medicaid spending next fiscal year. House and Senate health committees are trying to figure out how to accomplish this and squeeze other health programs under the low ceilings.

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The American Medical Association has called upon the Federal Trade Commission to junk its investigation of physician control and impact on Blue Shield plans.

Physicians' formal participation on the boards of open-panel medical prepayment plans has been declining since 1977, when the two FTC reports on the issue were concluded, the AMA noted in a statement to the Commission.

"An objective review of the current state of these plans' operations would support immediate termination of the staff investigation. Many public dollars have been spent to generate the staff reports and their somewhat simplistic analyses. This matter should be closed, and the boards of such plans commended for the substantial move in recent years to open to public view and control these medical plans."

By 1979 more than 60 percent of Blue Shield plans, representing 83 percent of total subscription income had non-physician majorities on their boards, the AMA noted. "Every year there is less and less reason to consider any rulemaking by FTC, much less litigation or other punitive action against these plans."

The AMA said there's no justification "for spending more public dollars to pursue FTC's speculation that any physician participation on these boards increases physician reimbursement levels and health care costs."

Physician leaders who have served on open-panel plans, the AMA said, have been able to bring pertinent experience to bear without undermining the public and subscribers' interest. "The beneficial impact of medical participation in these endeavors must be recognized."

Meanwhile, the Congress has granted the Federal Trade Commission a new lease on life, providing a formal three-year money authorization. The bill clips the controversial agency's wings by subjecting its decisions to a veto by Congress. Enactment of the measure followed a lengthy bitter dispute by members of Congress with the FTC, which lawmakers contended was overstepping authority in its all-out campaign to crack down on business and the professions.

******

The Justice Department has told Virginia health planners that some health planning agreements may be a violation of the federal antitrust laws.

The case involves a proposal to encourage Richmond, VA hospitals to take cooperative steps to reduce obstetric services.

The Central Virginia Health Systems Agency was told by the Justice Department that such proposed joint actions might come under the shadow of the antitrust laws unless specifically approved by Congress or state legislatures.

The advisory Justice Department letter has national implications on health planning activity and may force Congress to take another look at the wording of the law. The comment was termed a "very serious development that would run directly contrary to what the Congress intended," by the American Health Planning Association.

A Richmond hospital group had challenged the obstetric proposal, claiming it could inhibit competition and new services. As a result, the Justice Department was asked to express its views.

The problem was bound to arrive sooner or later since health planning decisions often run contrary to the assumptions of a competitive health marketplace.

******

Facilities planning to reduce bed capacity or services should not have to seek certificate-of-need approval by planning authorities, the AMA has told the Health and Human Services Department.

(continued on page 455)

Prepared by the Washington, D.C.
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Commenting on proposed regulations to carry out changes in the planning law, the AMA said "such application of the certificate-of-need program could force an institution to keep beds and maintain a service even though it might deem it inappropriate and infeasible to do so. This would seem to be holding the institution in bondage."

Congress' concern in the planning law was increases, not decreases, the AMA noted.

Also questioned by the AMA was the wording of the new regulation extending certificate-of-need to purchase of expensive equipment (more than $150,000) for physicians' offices if the equipment is designed in large part for use by hospital inpatients. The requirement for "irregular" use only for inpatients is too inflexible since it would apply to such cases as an agreement with a hospital to use the office equipment when the hospital equipment is undergoing regularly scheduled maintenance, the AMA said.

The AMA said it was "strongly concerned" with a requirement that the state planning agency consider the quality of care in an institution as an element in certificate-of-need determination. The actual determination of quality should be resolved by agencies such as the Joint Commission on Accreditation of Hospitals, state licensing authorities, and professional standards review organizations, said the AMA.

******

President Carter is reported ready to order a stringent clampdown on all hospital construction and renovation involving federal funds. Almost $1 billion of building and renovation planned for federal hospitals might be cancelled.

The impact on non-government hospital construction would be far greater.

The presidential action would be the most dramatic step taken by President Carter against adding hospital beds. The Administration has contended there are 130,000 unneeded beds in the nation and that adding to the supply is wasteful, costing the country $4 billion annually.

One of the prime weapons against new hospitals could be the threat of withholding Medicare and Medicaid payments for capital costs, a $2.3 billion budget item next fiscal year. Other federal aid that could be shut off includes federal grants, loan guarantees and loans administered through a variety of agencies. Consideration is being given to action against issuance of tax-exempt bonds for hospitals in surplus areas.

The government estimates there are too many beds at present in 196 of the nation's 213 health service areas. Thus, this Administration policy could affect construction and renovation in most areas of the country. The policy would not hit construction in areas found to need beds.

The proposal to move against hospital construction is thought to have been in the works for several months with the White House, the Office of Management and Budget, and the Health and Human Services Department working on the plan. One reason for the proposed action is the failure of Congress so far to enact the Administration's Hospital Cost Containment plan which included a limit on capital spending.

******

In trouble on Capitol Hill is the federal government's long-standing program of money for medical schools based on the number of students.

A sharp reduction in the so-called capitation aid was contained in the Health Manpower bill approved recently by the House Commerce Committee. There are strong pressures in the Senate to whittle the aid program.

Not only are medical schools under the gun from the authorizing committees—House Commerce and Senate Human Resources—but the appropriations committees are eyeing cutbacks.

The Carter Administration wants to kill capitation aid, arguing that the number of physicians is becoming ample and that it is time for the government to start easing back on the financial aid launched more than a decade ago to expand the physician supply. There have been veto threats raised if Congress approves legislation providing more than the $425 million the Administration has asked for the entire medical manpower package.

The Commerce Committee bill goes over the budget, authorizing $649 million, though it pares the capitation program, authorizing over the next three fiscal years $61 million, $40 million, and $20 million.

Present level is $81 million.

Meantime, acting under severe budget pressures, the Senate Appropriations Committee has agreed to cut $40 million of currently-allocated funds for capitation payments. Acting on the same budget rescission and supplemental appropriations bill, the House Appropriations Committee rebuffed the Administration's request to eliminate the capitation money.

A House-Senate conference probably will be needed to determine whether current capitation appropriations can survive intact.

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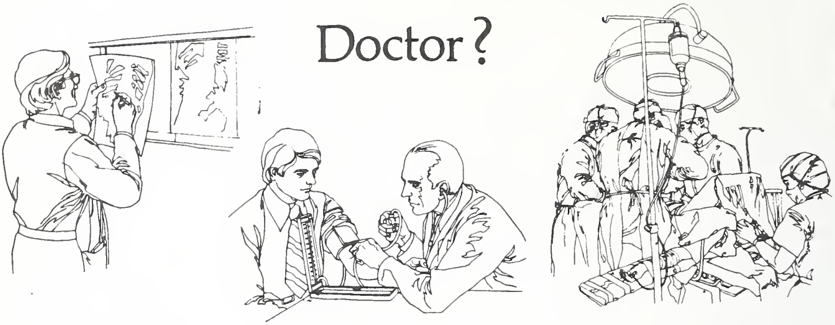
Leonard Schaeffer has resigned as Administrator of the Health Care Financing Administration, the agency that operates the Medicare and Medicaid programs.

The announcement came as a surprise. Schaeffer, 35, was reported taking a position outside of government. His resignation was not believed to be on policy grounds nor due to any dispute with Patricia Harris, HHS Secretary.

Have you considered participation, Doctor?



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The President's Page

With increasing frequency, many institutions in American medicine have come under attack, the most recent being specialist certification and specialist societies. Certification was originated by organized medicine to recognize special qualifications so that consumers could be assured that a practitioner was indeed qualified, at least by training and examination. Specialty societies were created to support the growth of educational opportunities and scientific progress in the specialty. The system has worked very well, both to the benefit of the consumer and the advancement of each specialty.

The Federal Trade Commission has instituted action contending that restrictions of society membership, publications in society journals and hospital privileges based on certification are in restraint of trade. When the media describes conflicts between two specialty societies as to which should have exclusive privileges to do certain surgery (as in the case of plastic surgeons vs. ENT surgeons), it is evident that there is some validity to the FTC criticism.

The most disturbing trends result from the susceptibility of the certification structure to further government regulation. One New England legislature considered a measure to restrict psychiatrists to the practice of psychiatry only. What problems this could have created stretch the imagination. A specialty society actually introduced a resolution in the House of Delegates of the AMA last year that supported the Dept. of Health, Education and Welfare in a plan to have that agency set requirements for performing certain operations.

These are only two of many similar instances of state and national proposed regulations and controls, sometimes even originating from within medicine. Many of these are concerned with modification of licensure according to certification. Others have proposed regulations or takeover of the certification process including control of training programs and examinations. Perhaps the most threatening, and most frequently physician supported, have been numerous proposals to adjust fees by certification. There are raised disturbing visions of residency training programs becoming a vast bureaucracy, of limited licensure subject to political pressures and the political process, and of fees regulated by federal or state bureaus.

Some physicians have suggested that the entire system, especially certification, should be overhauled or perhaps even abolished. The principal argument is that discontinuation of the certification process, which is the Achilles' heel as far as regulation is concerned, would not significantly alter the present specialty training programs or the status of the well qualified physician or the effectiveness of the specialty societies. Other physicians have supported a continued government invasion of these processes. Most physicians, we trust, have faith in our present specialty system and would prefer to see it preserved and strengthened.

To accomplish this, physicians must become aware of the pressures on specialty societies by the Federal Trade Commission and other agencies, and of government erosion of training programs and the imminent dangers of bureaucratic control of certification and licensure. The certification process must remain in the hands of competent medical boards. Licensure must be kept independent of certification and political processes. Fees should depend on services rendered and not on who renders the services. Physicians must also look to the strengthening of the system from within. Certification must be as broadly based as possible so that all truly qualified may be certified. Training programs must be planned and administered by competent physicians. Specialty societies must avoid unionism.

The changes in our specialist system have been subtle and poorly understood. Greater thought must be given to this area so that our actions in the future will be constructive and effective.

W. Raymond James, M.D.
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Reflections from the Dean's Office

"Things Are in the Saddle"

ROBERT U. MASSEY, M.D.

Man's technology, what it does and how much it costs, has dominated the talk of economists, political scientists, philosophers, poets, engineers, and scientists for a century at least. Most of us who grew up with twentieth century technology probably did not think much about it, except to be proud that Americans invented so many useful things. After World War II, we worried about the Bomb and then about television and its effects on our children's minds; suddenly a whole mass of problems about highways, pollution, nuclear energy, and the relations between technology and political power have been raised, and nobody seems ready with explanations or even very good questions.

While science and technology represent separate human endeavors and follow different rules, they are related in our heads; thought and act, mind and hand are too closely linked to go on separately for long. Our ability to find out more about nature and to build new machines seems almost limitless. Victor Weisskopf wrote that, " — potentially, science can justifiably claim the ability to understand every observable phenomenon."[1]

New knowledge opens the way to new technologies; these new tools are the means to new knowledge, and so almost *ad infinitum,* the "almost" having to do with how far we are willing to push our materialism.

Our science is at most a tenth as old as our civilization which, as far as we can tell, has been around for less than one percent of the time that we have had our present kind of central nervous systems. We have hardly begun, and it is difficult to imagine limits.

And yet there are doomsayers. Philip Handler, in a recent editorial in *Science,*[2] says that, "The intellectual elite in every era has always been pessimistic." There seems everywhere to be an increasing antiscience and antitechnology mood that may be more than recurring nineteenth century romanticism. It has to do with fears not easily put to rest; Goethe was haunted by the Faust legend most of his life; this matter of the good and evil uses of knowledge lies at the heart of his drama. There are hard philosophical problems that are not passed over by saying that science and technology are morally neutral.

In medicine it should not be so difficult. Our technologies have been mostly beneficient and have been, in Bacon's words. "for the use of life". Stethoscopes, clinical thermometers, poliomyelitis vaccine, and even CT scanners do not sully the neighborhood, dirty the water, or provide anyone with undue political power. On the surface, they raise no serious philosophical questions.

There are problems, nonetheless. Technologies which should be means have a way of becoming ends. Sometimes we forget to ask what the technology is for or why the answer is worth having. Howard Spiro writes, "Gastroenterologists and radiologists, trading plastic cards and pictures, sometimes look very much like the boys of my youth trading baseball cards."[3] We are worried about how this love affair with machines, images, and numbers may dull the edge of our clinical acumen, make us brokers between people and machines, create ugly bureaucracies, and drive up the cost of care.

This last is the least important; at most, it qualifies only as a symptom. Most technologies, properly used, are cheaper than those they replace; effective technologies like vaccines are cheapest and best of all.

If technology adds to cost without improving care, it does so in the little decisions made thousands of times every day—questions that are put to machines and laboratory technicians whose answers make no difference. The regulators do not know how to get at that, but they can limit the availability of the big and effective technologies that do make a difference but probably add little to costs.

Better education in the skillful and artistic use of existing technologies is half the answer; more research to get better explanations of biology and more powerful technologies, which are almost always cheaper, is the other half. Attacking the symptom of dollar costs head on may make everything worse by taking away initiative, increasing real costs, and dismantling a system of medical care that for all its faults is the best in the world.

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

Physicians' Obligations to Maintain Privacy and Confidentiality III: Current Controversies

JOSEPH M. HEALEY, J.D.

The difficulties encountered by physicians in evaluating their obligations to disclose or to refrain from disclosing information obtained during the doctor-patient relationship are highlighted by three current controversies: the reporting of child abuse and neglect cases as required by state statute; public disclosure of the health status of presidential candidates and congressional access to the Shah's medical record. It is not difficult to see how these controversies have arisen. During the past decade, we have come to see how widespread and insidious problems the abuse and neglect of children really are. During the presidential year, we have had raised again the question of health and physical fitness among those who would be president. Few episodes in recent American diplomatic history have had the disastrous consequences as the decision to admit the Shah of Iran to the United States for medical care. In each case, however, counterveiling claims of confidentiality or privacy have been raised to block disclosure of information. These three cases provide a good context to conclude our three-part discussion of physicians' obligations in this sensitive area.

A common bond in all three cases is a tension between the privacy and confidentiality usually afforded patients in the health care process and the existence of a public need to know or a public benefit from knowing. Since none of these concepts is absolute and since each must be viewed in the context of concrete situations, few generalizations of any value can be advanced. In the first case, protection of a child from injury or re-injury is a primary goal of mandatory abuse and neglect reporting statutes. Yet, for a variety of reasons, physicians have tended to under-report cases. Some allege that the concepts of abuse and neglect are too vague to justify state intervention. Others allege that the family's right to privacy outweighs all other concerns. Others allege that to report abuse and neglect cases would violate confidentiality owed parents and undermine the rehabilitation of parents with serious problems. In the second case, there is no doubt that fitness for public office, especially the presidency, includes the health status of the candidate. Yet what might result if there were no confidentiality between physician and the patient-candidate? Would patients be reluctant to discuss any early symptoms which might make possible early detection and elimination of disease? Would physicians become manipulators of information simply to provide the patient-candidate the same confidentiality available to other patients? In the third case, undoubtedly the Carter Administration's handling of the Iran situation will be the subject of examination and review. One critical piece of the puzzle will be the accuracy of the decision to admit the Shah into the United States for medical treatment. Should the Shah's record be available for a congressional committee or should the hospital and physicians be allowed to cloak their actions with a veil of confidentiality? I suspect we all have strong feelings about this issue, but have we given serious enough thought to the consequences of allowing a congressional committee power to reach even these most sensitive documents? Again, the problem is puzzling and the answers are not self-evident.

In the end, we are left in the uncomfortable position of uncertainty. How is a physician to know what to do about problems in confidentiality and privacy? More generally, how is a physician to know how to deal with the enormous legal issues which also admit no simple answer. I believe the key is to be found in the appropriate integration of legal consultation into one's practice as a physician. This process will be the subject of next month's column.

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EDITORIALS

Educational Programs in Cardiopulmonary Resuscitation for Physicians—Revisited

Physicians working full time in emergency rooms and in coronary and intensive care units are repeatedly exposed to the problems of cardiopulmonary resuscitation (CPR), and are well prepared for applying its techniques. Attending staff physicians, usually nonhospital based and in private practice, are less frequently exposed to the likelihood of needing to perform CPR, and thus have reduced opportunities to master its problems and learn its skills. Physicians, however, should not be exempt from knowledge of a procedure that in the hands of other groups, including paramedics and bystanders to a cardiac arrest, has been shown to have a significant impact upon improved survival.[1-3] Since competence in CPR can best be maintained only by repeated practice and review, hospitals and their medical educational programs have become increasingly involved in providing such learning processes for attending physicians on their staffs.

The results of a 1972 survey questionnaire from 41 Connecticut hospitals indicated that 15 institutions, about 1/3, provided an educational program in CPR for their attending physicians, with both larger and smaller hospitals equally represented.[4] Four institutions responded that this instruction was mandatory, in two of which it was so indicated in the hospitals' bylaws or regulations.

In order to learn whether additional educational programs in CPR have been developed since this initial study, the questionnaire was resubmitted to the directors or administrators of the same hospitals seven years later. The pertinent questions were the same as those previously asked: (1) Does your hospital have a program of instruction in CPR for its attending physicians? (2) If so, is participation mandatory? and (3) Is there a hospital bylaw or regulation concerning this? Twenty nine of the 41 hospitals replied that such a CPR program of instruction was now available. Eleven of the institutions indicated that regular attendance at these programs, either yearly or every other year, was mandatory. This was so stated in a bylaw that was either in effect or being developed in nine of these hospitals.

The accompanying table compares the result of the recent study with that performed in 1972. The number of hospitals with CPR programs for their attending medical staffs approximately doubled over the seven year period, while the number of institutions responding that attendance was mandatory almost tripled. There was also a comparable increase in the number of hospitals indicating that there was now a bylaw or regulation either being developed or in effect requiring such participation. No attempt was made at this time to analyze program content which varied widely from hospital to hospital.

Many reasons can account for this change, amongst which might be cited greater physician interest, physician concern with medical-legal responsibilities, and public expectations. In addition, the responsibility of the hospital towards its patient population has in turn placed an obligation upon the medical staff, reinforced by the statement from the Joint Commission of Accreditation of Hospitals that . . . "There should be evidence that all medical staff members have participated in basic cardiopulmonary resuscitation training and are considered so qualified."[5]

In summary, the number of hospital based CPR training programs provided for attending physicians at the major institutions in Connecticut doubled between 1972 and 1979, with greater emphasis upon assuring participation. Although documentation of the efficacy of such programs upon patient survival might be difficult, interested and concerned physicians are aware that only through such processes can their professional responsibilities be maintained. As stated by Carden—"Who among us can exempt himself from that category?"[6]

QUESTIONNAIRE RESPONSE TO CPR SURVEY
IN 41 CONNECTICUT HOSPITALS

	1972[4]	*1979*
Number of hospitals with CPR programs for attending physicians	15	29
Number of hospitals in which attendance is mandatory	4	11
Number of hospitals in which mandatory attendance was stated in a bylaw or regulation	2	9*

*Four of these hospitals stated that a regulation or bylaw was in the process of being acted upon or developed.

Martin Duke, M.D.

Manchester, CT

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Cancer of the Breast— The Patient's Viewpoint

There is no disease in our country that produces more emotional discussion among surgeons and patients than treatment of cancer of the breast. In this issue are articles by two patients—both lay persons, highly intelligent and knowledgeable, both medical writers. It is worthwhile for any physician who treats breast cancer to read their viewpoint.

Rose Kushner is a member of the Consensus Development Program at the National Institutes of Health. This program by NIH was initiated in September 1977 to "put into place a program aimed at improving the translation of the results of biomedical research pertinent to health care and to knowledge that could be used effectively in the practice of medicine and in public health." A key element of this effort are the reports of the Consensus Development Conference. To date, more than two dozen consensus statements have been published, as "useful information to practicing physicians and biomedical scientists as well as the general public."

It remains to be seen whether these statements will be used as guidelines or standards or even as regulations by the federal government, for example in Medicare and Medicaid. And it would seem logical that trial lawyers may use them as useful information in malpractice when it suits their purpose.

One of the early reports was on the treatment of Primary Breast Cancer: "The consensus of the panel that a procedure which preserved the pectoral muscles, i.e., a total mastectomy with axillary dissection, provides equivalent benefit to women who have Stage I and selected Stage II breast cancer. Therefore, total mastectomy with axillary dissection should be recognized as the current treatment standard. It was also the consensus that a two-step procedure should be done in most cases, i.e., a diagnostic biopsy should be studied by permanent histologic sections before definitive therapeutic alternatives are discussed with the patient."

At least one political body, the Massachusetts Legislature, has gotten into the act. In legislating patients' rights into statutory form, it has included a provision related to cancer of the breast. The law states that "A patient suffering from any form of breast cancer shall be provided complete information on all alternative treatments which are medically viable. And any person whose rights under this section are violated may bring . . . a civil action"—as outlined in a statutory provision.

Grant V. Rodkey, M.D., President of the Massachusetts Medical Society and general surgeon on the staff of the Massachusetts General Hospital, stated in his comments before the Health Care Committee of the State Legislature, that "alternative methods of treatment of breast cancer are not all equal, and they are not all applicable in the case of any individual patient." His statement reflects a difficulty and even impossibility for the conscientious physician to give a consensus statement of the entire course of treatment for an individual patient with cancer of the breast.

Rose Kushner herself essentially agrees with him that the tables she includes in her article raise more questions about the treatment of breast cancer in women's minds than they answer.

A good case, at least psychologically from the patient's viewpoint, can be made for the two-stage procedure, and even for a surgeon. It certainly is easier to tell a patient with a lump in the breast "Let's take a piece of this lump for examination to find out its exact nature" and then to discuss your treatment than to explain the various modalities available if one is to rely on a frozen section diagnosis. Explanation will not be easier if one of the alternatives required by statutory "complete information" is the performance of reconstructive procedures at the time of the mastectomy. There are other reasons to eliminate the traditional frozen section procedure besides the fact that 80-90% of such lumps are negative for cancer. Crucial to informed consent is the trust between the surgeon and patient, so well described by Helen Lillie.

Physicians always need remind themselves that a patient ethically and legally has a right to do with her body as she wishes. It is difficult and time-consuming for a surgeon and oncologist to discuss even reasonably the many alternatives in the treatment of cancer of the breast. Scientifically it may become more complicated in coming years, and also as women themselves become more knowledgeable. One might make a good case for the training of more women surgeons and oncologists to specialize in treatment of cancer of the breast.

Fred Fabro, M.D.

Letters to the Editor

NEW HAVEN COUNTY FOUNDATION

To the Editor: Dr. Ronald Savin is definitely not alone in his assessment of the New Haven County Foundation. My experience with that organization, both as a patient and as a participating specialist, has been that it is a restrictive organization which basically prevents "free choice" for patient and physician. The rules have definitely been changed since the original contract was signed. It has been my personal experience that the administration of the Foundation will use any excuse possible to avoid paying legitimate claims.

As a patient, on one occasion I went to the emergency room at the Hospital of St. Raphael with sudden onset of pleuritic chest pain, after normal office hours. I was examined by one of the emergency room physicians who happens to be a friend of mine. He ordered an X-ray without bothering to fill out a formal emergency room form. The Foundation refused to pay for the X-ray because of the lack of the emergency room form. In effect, the absence of the emergency room form saved the Foundation the fee for an emergency room visit and, therefore, helped reduce costs; however, they have persistently refused to pay for the X-ray.

On a second occasion, I injured my knee and I self-referred myself to a participating orthopedist. Because I did not go through a primary care physician, the fee for the orthopedist and the X-rays was also rejected. Had I gone to a primary care physician, there would have been his fee as well as the specialty fees, however, by my self-referral, I gave the administration of the Foundation all the excuse they needed to reject the claim.

In this latter instance, the orthopedist and the radiologist certainly should have been paid by the Foundation.

As a direct result of this kind of administration, I have removed my family from membership in the Foundation as patients and I have removed myself from participation in the Foundation as a participating physician.

Jeffrey D. Gold, M.D.

New Haven, CT

BOOK REVIEW

Philosophy and Medicine: a book series. Edited by H. Tristram Engelhardt, Jr. and Stuart F. Spicker. D. Reidel Publishing Co., Dordrecht-Holland/Boston-U.S.A. Evaluation and Explanation in Biomedical Sciences, Vol. I 240 pp., 1975. $31.60; Philosophical Dimensions of the Neuro-Medical Sciences, Vol. II 274 pp., 1976. $34.25; Philosophical Medical Ethics: Its Nature and Significance, Vol. III 256 pp., 1977. $28.95; Mental Health: Philosophical Perspectives, Vol. IV 302 pp., 1978. $28.95; Mental Illness: Law and Public Policy, Vol. V 276 pp., 1980. $28.95. (not reviewed here); Clinical Judgement: A Critical Appraisal, Vol. VI 271 pp., 1979. $29.50.

The philosopher's concern with medicine is perennial and has roots in antiquity. Today it is possible that philosophers and physicians might find some points of agreement along the way, but it would be a mistake to begin with that assumption. And thus in the early seventies, when medicine became an examined-profession, Engelhardt and Spicker perceived a need to create a formal dialogue between philosophers and physicians in a critical and systematic way. Their efforts evolved into a unique group of ongoing symposia held at different medical schools, here and abroad. Eventually this led to the publication of a seminal series of six volumes, called *Philosophy and Medicine.*

Volume I examines the philosophy of medicine as a definable discipline. Philosophy asks whether medicine, a so-called derivative science, is approachable as an art, and how medicine perceives itself as a science. As the medical historian attempts to describe change and offers explanations and interpretations, the philosopher offers explanatory models. One such model is the "concept of disease" in which Engelhardt, in a germinal essay describes a general schema for explaining, predicting, and controlling. The question of whether science is essentially value-free and medicine value-laden is argued by S. Toulmin. M. Wartofsky presents disease as a social and historical phenomenon.

In Volume II the role of Cartesian (mind-body) ideas is explored together with the concept of hemispheric dominance in mind-body relationship. Pain is examined as an existential symptom and psychosurgery is explored philosophically. Dr. Ian Lawson offers a superb account of what it is to be impaired after hemispheric injury. He suggests that the clinician must enter into a kind . . . "cerebral symbiosis with braindamaged patients: learning most from the ingenuity with which a residual brain circumvents and substitutes for its own disability". It is our duty to enter the patient's world in order to help him to better achieve his lessened-humanity as a significantly altered person.

Volume III is concerned with the nature and significance of medical ethics. Chester Burns suggests that medical ethics would be non-dimensional without the study of medical history. Professional medical ethics concentrates on the interrelationships between persons, while bioethics focuses on the interactions between technological possibilities and human values (E. Pellegrino). There is an excellent selection of essays on the following subjects: euthanasia, "pulling the plug", defining death, consent, and experimentation.

Volume IV deals with the philosophic perspectives of mental health. Mental health remains an endorsement of one's general success in adapting to one's environment as well as one's culture. Dr. Szasz, a rhetoretician, argues that mental diseases are actually problematic ways of living which are assumed by individuals. Mental disease, as a myth, allows the reclassification of symptoms for socially useful purposes. The semantics of mental health is complex, but is well developed in the essays.

Volume V, *Mental Illness: Law and Public Policy* has not been released from the press.

Volume VI deals with the concept of "clinical judgment". It refers to the capacity to make medical judgments about patients. It may also be used as an arrogation by the physician as a final justification of diagnosis and treatment. One writer suggests that clinicians are often by temperment ill-suited to form logical or mathematical accounts. There are several essays on the logic of clinical judgment which offer a disciplined analysis and construction of the process of medical reasoning. However, clinical decisions can be made more rigorously logical without reducing everything to algorithms and regressive equations. The problem of "subjective information" is discussed by Dr. Eric Cassell.

For those of us who profess to be healers, the practice of medicine is what each of us is pleased to think it to be. It has been this tentativeness together with the shifting views of what constitutes health and disease, and of what medicine's role ought to be, which has intrigued the philosopher.

Stuart Spicker and H. Tristram Engelhardt, Jr. have skillfully organized the symposia and have focused on a wide range of concepts and issues in a venture which has invited scholarly scrutinization of the general conceptual presuppositions which structure the activities of medicine. It is obvious that medicine cannot examine itself. *Philosophy and Medicine* is a scholarly attempt to open doors and build bridges.

Ray Schipke, M.D.

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AMA, Medical and Health News

AMA dues will not be raised in 1981. After reviewing the success of the Association's five-year financial plan, the Board of Trustees voted not to seek a dues increase at the Annual Meeting of the House of Delegates in July. "The fiscal and performance controls developed by the Board and senior management over the past five years, together with efforts to increase revenues from sources other than dues, have been successful," said Board Chairman Lowell H. Steen, M.D. "So far, in spite of the highest inflation in history, the payment of taxes on unrelated business income and costly litigation, we have managed to keep in balance." Since January 1, 1976, AMA dues have been $250 annually for regular members, $35 for interns and residents, and $15 for students.

The AMA will serve as a national clearinghouse for information on errant physicians, in an effort to help state licensing boards provide an orderly and effective pattern of medical discipline. AMA President Hoyt D. Gardner, M.D., told the Federation of State Medical Boards of the United States: "The AMA wants to be notified of all license revocations and other disciplinary actions taken by state boards. In this way, it can help keep serious offenders of one state from abusing the medical and hospital privileges of another state." Dr. Gardner called for more states to finance their medical boards through licensing fees rather than through general revenue, thus making the boards less subject to political pressure.

The AMA is unable to support Council on Wage and Price Stability guidelines that limit the rate of increase in physicians' fees in 1980 to 6.5%. The rate of inflation appears to be about 18%, the AMA pointed out, and the COWPS wage guidelines for industry are 7.5% to 9.5%. At a meeting of leaders of the Voluntary Effort to Contain Health Care Costs and HEW officials, the AMA said it would continue to urge individual physicians to exercise restraint, a policy that has resulted in fee increases well behind the Consumer Price Index figures for the economy in general.

"Guidelines for Prescribers of Controlled Substance," a series of suggested principles approved by the AMA and six other health organizations, were issued April 7 by the federal Drug Enforcement Administration. The principles were developed by the DEA's Practitioners Working Committee, which was formed in 1974 and includes the AMA, American Dental Assn., American Nurses Assn., American Osteopathic Assn., American Podiatry Assn., American Veterinary Medical Assn., and the National Institute on Drug Abuse. The voluntary guidelines were approved by the AMA House of Delegates at the 1979 Interim Meeting. Copies of the guidelines have been sent by the AMA to state, metropolitan county and specialty societies. Additional copies are available from Dept. of Mental Health, AMA Headquarters.

A new AMA book on the impaired resident physician is the result of a study begun in 1976 by the AMA Resident Physician Section's Work Group on Physician Well-Being. The 125-page *Beyond Survival* reviews the literature, describes model programs for helping and preventing impairment, lists national, state and other resources, and contains an annotated bibliography. *Beyond Survival* also describes techniques for impairment identification, confrontation, rehabilitation and reentry. Cost is $5 for 1-10 copies; $4 for 11-49; $3.75 for 50 or more; and $7 for foreign orders. Orders must be prepaid. Write OP-083, AMA Order Dept., P.O. Box 821, Monroe, Wis. 53566.

Opinions and attitudes about AMA membership will be asked of 10,000 physicians in a survey being conducted for the AMA Office of Membership Development by the AMA Dept. of Survey Design and Analysis. The four-page questionnaire was mailed in April to a sample of member and nonmember physicians, including 2,000 women physicians and 2,000 foreign medical graduates. Physicians are urged to cooperate in completing and returning the questionnaires. Participation will give many physicians an opportunity to be heard at the national level of organized medicine. All responses will be handled in strict confidence and only aggregate results will be used.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Public Affairs

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Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

COUNCIL MEETING

Wednesday, June 11, 1980

Attendance

Present were: Drs. James, Canzonetti, Parrella, Backhus, Mendillo, Sadowski, Hess, Van Syckle, Whalen, Jr., Fabro, Cramer, Jameson, Anderson, Magram, Freedman, F. Barrett, Zlotsky, Doctor, Klimas, Abbot, J. Barrett, Tierney, Bobruff and Sonnen.

Also present: Mr. Norbeck, Mr. Sweeney, Mr. Brunell, Dr. Clare Callan and Mr. Tomat (FCMA).

Organizational Meeting

The organizational meeting of the Council for 1980-81 was called to order by the President, W. Raymond James. Following some opening remarks and the introduction of Council members and CSMS staff, elections of a Chairman and a Vice-Chairman of the Council for 1980-81 were held. Those elected: Chairman—Andrew J. Canzonetti, Waterbury; Vice-Chairman—Guy W. Van Syckle, Danbury.

Approval of Minutes

Note was made that the published minutes of the meeting of April 3, 1980, had been approved at the House of Delegates meeting on April 30, 1980, as part of the "Report of the Council."

Reports from Physicians Serving on State and Federal Agencies

Dr. Orvan Hess reported that the litigation between Yale-New Haven Hospital and the CCHHC had been resolved with some reduction in the number of beds. Dr. Francis Klimas reported on the failure of the Bridgeport HMO and mentioned that its debt to Blue Cross-Blue Shield was approximately $350,000. After a brief report by Dr. T. Peter Jameson on the status of the Greater Danbury Health Plan and further comments on the general subject of HMOs and IPAs, sentiment was expressed for having a panel discussion on that subject for the next Council meeting. It was suggested that Mr. Peter Aaronson (Executive Director of the New Haven County Medical Association Foundation for Medical Care), Mr. John Nelson (Executive Director of the Community Health Care Center Plan), and Ms. Dindy Harris (Danbury IPA) serve as panel members.

Report of the President

Following a verbal report on the 1980 Annual Meeting by Dr. W. Raymond James, it was VOTED to have the Subcommittee on Annual Meeting Arrangements discuss CSMS Annual Meeting arrangements for the purpose of developing new ideas to attract more physicians to subsequent meetings.

It was VOTED to refer the report of Mrs. Joseph Czarsty (President of the Auxiliary to the CSMS) to Drs. W. Raymond James and Andrew J. Canzonetti for review and consideration and a report back to the Council with any recommendations.

After discussion about a letter to Dr. James received from Mr. Joseph Marlowe, Chairman of the HSA Computed Tomography Task Force, it was VOTED that CSMS comply with the request to submit at least two names of physicians for each health service area to provide technical guidance to the Task Force. The names submitted are as follows: HSA I—Drs. Jerome Resnick, Stamford, and Robert Russo, Bridgeport; HSA II—Drs. Gerald Freedman, New Haven, and Robert Shapiro, New Haven; HSA III—Drs. Henry Brown, New London, Arthur L. Waldman, Cromwell, Robert S. Bell, Norwich, and Alan R. Melton, Willimantic; HSA IV—Drs. Thomas J. Spackman, Farmington, and Joseph Sadowski, Hartford; HSA V—Drs. Todd E. Anderson, Torrington, and Mehdi S. Eslami, Waterbury.

President James reported that the CSMS Committees on Drug Abuse and Mental Health had adopted a recommendation to the Council that the Ad Hoc Committee for Impaired Physicians be encouraged to work with the Connecticut State Medical Examining Board to investigate, and to seek to remedy cases of potential physician impairment, and to advise the Board concerning same, prior to the Board's instituting formal proceedings in such cases.

After discussion it was VOTED to endorse the efforts of the Ad Hoc Committee for Impaired Physicians to interrelate with the Connecticut State Medical Examining Board on matters relating to the "Impaired Physician." It was also VOTED to apprise all CSMS members, through Connecticut Medicine and CSMS Newsletter, of the reporting section of the statute relating to the Impaired Physician.

After a discussion of the current campaign for President of the American Medical Association, it was VOTED to endorse the candidacy of Dr. Thomas Ballantine, of Massachusetts, for the Presidency of the AMA and to notify all other state medical societies of that action.

Nurses Strike in Danbury

Drs. T. Peter Jameson and Guy W. Van Syckle discussed the recent nurses' strike in Danbury. They mentioned that other unions provided picketing support and nurses, union and non-union alike, from other parts of the state joined in that effort. The nurses' complaints against Danbury Hospital included their level of compensation, vacation time, a lack of input into the administration, few incentives, limited opportunities for progression through the ranks, and interest in having a union shop.

The 405 bed hospital found it necessary to immediately reduce its capacity to 185 beds and the pediatrics and renal dialysis units were forced to close down during the strike. All elective surgery came to a halt as well. It was mentioned that the physicians on the staff of Danbury Hospital did not take sides during the conflict, and this was believed to be a very positive sign. The strike cost the hospital approximately $45,000 - $50,000 a day and seemed to be especially difficult on the patients and surgeons.

NOTE: A tentative agreement was reached on June 10 between the nurses and the hospital, and the agreement was ratified by the nurses on the evening of June 11.

Health Maintenance Organizations

Dr. Sidney L. Cramer reported on a HMO meeting held in New Haven on May 14 which had been sponsored by the Greater New Haven Chamber of Commerce, Blue Cross & Blue Shield of Connecticut, the Association of Connecticut Health Maintenance Organization and the Fairfield-Westchester Business Group on Health. It was agreed that a seminar on the subject at the next Council meeting would be most appropriate.

Committee on Statewide Medical Planning

The Council was apprised of the committee's recommendation to appoint a committee to meet with the Commissioner of Health to explore matters of common interest in the health field. After discussion, it was VOTED to refer Commissioner Lloyd's communications to the CSMS Committee on Public Health for review and a report back to the Council in August with any recommendations.

Committee on Professional Liability

The Council discussed the committee request of the appointment of a panel of physicians to advise Aetna concerning the insurability of physicians. It was VOTED to appoint an appeals panel excluding members of the Professional Liability Committee and its district review panels. Following that action, Drs. Herbert M. Magram, William A. Whalen, Frederick C. Barrett and Sidney L. Cramer were appointed to the panel.

It was also VOTED to appoint a subcommittee of the Professional Liability Committee to review the proposed guidelines on insurability review. The Council appointed Drs. Lawrence Ahrens, Gioacchio Parrella, J. Alfred Fabro and Donald Glugover as members of the subcommittee.

Council Subcommittees

After a discussion of the organizational meeting format employed by the Council, it was VOTED to have all Subcommittees of the Council remain functioning through the organizational meeting so that there is no interruption of subcommittee activities due to the organizational meeting.

AMA Negotiations Seminar

Mr. Norbeck discussed the possibility of having the AMA present a Negotiations Seminar in the fall to the Council in New Haven. The cost of such a seminar would be $2,000 and would accommodate 25-30 physicians over a period of one and a half days. Mr. Norbeck was asked to attempt to secure a Friday and half a Saturday in October, if possible, and to report back to the Council at its August meeting.

Request from Department of Motor Vehicles

After a brief discussion, it was VOTED to comply with Commissioner Benjamin A. Muzio's request for submission of the names of fifteen physicians who would be willing to serve on a Medical Advisory Board to the Commissioner of Motor Vehicles.

Selection of Site and Date for Semi-Annual Meeting

It was VOTED to hold the CSMS Semi-Annual meeting at the Lord Cromwell Inn, Cromwell, with preferred dates of November 20, 13 or 14.

Miscellaneous

It was VOTED that the Chairman of the Connecticut Medical Examining Board or his designate be invited to give an annual report to the CSMS House of Delegates meeting.

Date of Next Meeting

The next Council meeting is scheduled for Thursday, August 14, 1980.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on June 11, 1980. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

Fine Needle Aspiration of Lung Lesions: Observations by a Pathologist

RICHARD D. OTIS, M.D.

As we enter the new decade of the nineteen eighties, the growth and increased sophistication of pulmonary medicine continues. Changing disease patterns have made tuberculosis a relatively minor problem and promoted primary lung cancer to the status of a virtual epidemic. During the past decade we have witnessed tremendous improvement in the diagnosis of this disease from fiberoptic bronchoscopy and bronchial brushings. These techniques have enlarged the previous endoscopic limitations of the rigid bronchoscope especially in proximal lesions. The peripheral lesion still remained a problem in diagnosis, however, with many "coin lesions" not diagnosed until after thoracotomy and excision. Such lesions are ideal subjects for fine needle aspiration and cytological diagnosis.[1,2,3] The benefits to the patient from more rational planning of therapy are self evident. For example, current chemotherapy and radiation treatment can be instituted in the case of small cell (oat cell) carcinoma without the necessity of thoracotomy.

Despite its seeming simplicity, fine needle aspiration of lung lesions is still not widely used. The Scandinavian experience in needle aspirations of all manner of neoplasms in various organs is well known but, as discussed by Fox[4] and Koss,[5] has had limited acceptance in other medically advanced countries including USA. As applied to such organs as the breast, the technique was utilized and reported fifty years ago by Martin and Ellis[6] as well as Stewart.[7] Part of the problem now as in the past has been trained personnel. The surgeon is more at home with the scalpel under direct vision than with the seemingly blindly directed needle. Until recently, the internist has had more of a predilection for cerebral activities than for technical procedures. Certainly this was true of the radiologist who much preferred looking at a chest film to actually laying hands on the patient. Finally the pathologist was and regrettably often still is of little help, being happily sequestered in his laboratory. If he is an anatomical or surgical pathologist he is more secure with gross and microscopic analysis of tissue, following the well traveled path of Rudolph Virchow. In fact some clinical pathologists seem more enamoured of automated analytic instruments than of mere cells! This is in large part due to lack of experience and training. Certainly adequate training in cytopathology has always been a weak point in even the best of pathology training programs. The pathology resident actively participated in autopsies, described gross and microscopic surgical specimens and performed frozen sections as part of the team. In his limited exposure to cytology he was too often a "fifth wheel" in the diagnostic process. His participation tended to be of a passive nature and was sandwiched between other time demands. Fortunately training is improving as reflected in both residency and certification requirements.[8] A few pathologists have actually ventured to the patients' bedside to perform aspirations.[9] This is in line with the Swedish experience where the cytopathologist not only performs needle aspirations but also interprets them. Given our own situation and malpractice climate, the pathologist, unless especially trained, is probably best advised to limit himself to interpretation and diagnosis. The radiologist, however, is in a unique position to perform fine needle aspirations. With the advent of new radiologic and related techniques, he has an unparalleled opportunity. Ultrasonic and computed tomography guidance are applicable to aspirations of multiple sites including liver, retroperitoneum, pelvic masses, pancreas and thyroid.[10] The application of image intensification telefluoroscopy to transthoracic lung needle aspiration has revolutionized the primary diagnosis of lung masses by allowing rapid accurate diagnosis with minimal morbidity. The radiologist rather than the surgeon or internist has the best access to and

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RICHARD D. OTIS, M.D., Director of Anatomic Pathology, Hartford Hospital.

control of these new instruments. There is a symbiotic relationship between these techniques and cytopathology. Close communication is vital just as it is in the diagnosis of bone tumors.

It is to be anticipated that with the installation of a high resolution CAT scanner, the pathologist will be called upon in the same manner as he is by the surgeon for frozen section diagnosis. In fact, in planning the new body CAT scanner facility at Hartford Hospital, space has been alloted for cytology activities in the area. The space needs are modest requiring only room for slide preparation and for the dual head microscope to be used by the assigned cytologist and cytopathologist on call. Adequacy of material can be immediately evaluated and repeat aspiration performed if necessary. The team approach is enhanced with greater appreciation of individual and joint problems. Although general surgeons perform most of the breast aspirations at Hartford Hospital and both internists and surgeons perform thyroid aspirations, the vast majority of lung aspirates are done by the radiology group.

The use of a 20 gauge 2-piece thin wall slotted needle* under fluoroscopic control produces highly satisfactory material for cytologic evaluation. The slot creates a second cutting edge in addition to the needle tip resulting in small tissue bits for histologic processing in approximately 50% of biopsies. In little more time than it takes to do a frozen section, a smear can be stained by standard Hematoxylin and Eosin technique and reported. Ground glass slides for cell retention and alcohol fixation is used. As many as six to eight smears may be prepared from one aspiration. To reduce screening time, these are distributed to different cytologists for simultaneous screening but in most cases direct evaluation by one experienced cytologist or by the final evaluator, the cytopathologist, is feasible. Submission of tissue fragments, when obtained, to the surgical pathology service results in a further evaluation 24 hours later. The diagnostic correlation between cytology and histopathology has been excellent. The differences have been largely ones of semantics.

In considering lung needle biopsy procedures, it should be realized that the fine needle virtually eliminates the risk of hemorrhage. Four aspirations of thoracic aortic aneurysms simulating pulmonary masses were noted in our series without adverse reaction. Minor hemoptysis occurred in 8% of lung aspirations. Pneumothorax has not been a problem. It has occurred in 27% of the cases with 10% requiring some treatment, usually insertion of a 16 gauge needle with a 1-way Heimlich valve.[11] We have encountered no instance of tumor spread along a needle tract. As pointed out by Fox, this has not occurred in the Swedish experience using fine needle techniques. Older experience with coring biopsy needles in other sites is not applicable.

We have been most impressed with the results of this new technique. At Hartford Hospital 691 lung needle aspirations were performed on 543 patients from January, 1973 to October, 1978. 384 specimens from 368 patients were interpreted cytologically as conclusive for malignancy with an accuracy rate of 94%. 58 specimens were called suspicious for malignancy; 34 on subsequent needle aspirations to be positive. Westcott is reporting a subset of this series comprising a slightly different time period (October, 1975—December, 1978).[13] This is a group of 432 lung needle biopsies performed in 422 patients as a personal series. The results are comparable to the entire series with an accuracy rate of 96.5%. The four false positives consisted of patients with (1) pulmonary infarct, (2) radiation fibrosis, (3) organizing pneumonia, and (4) Cryptococcus neoformans granuloma. These cases and five false negatives are discussed in detail in his paper. The problem of false negatives can be reduced to a minimum if both operator and pathologist are satisfied that the aspirated material is truly representative. If not, the aspiration should be repeated at once.

When one considers the patients with benign lesions or non-resectable cancers who can be spared surgery by fine needle lung aspiration, the cost benefit ratios are indeed impressive.

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* Becton Dickinson Company, Rutherford, New Jersey. 20 gauge 2-piece thin wall slotted needle, #SH-2902.

Fiberoptic Bronchoscopy and Lung Biopsy

G. J. WALKER SMITH, M.D. AND ANTHONY M. COSTRINI, M.D.

ABSTRACT—For approximately a decade the fiberoptic bronchoscope has been available to physicians for the investigation of lung disease. While the rigid bronchoscope remains a valuable diagnostic tool, the flexible fiberscope allows inspection of airways to the subsegmental level and offers the additional advantage of allowing peripheral endobronchial or transbronchial biopsy. A wide variety of focal and diffuse diseases may be specifically diagnosed using this technique. Due to a low rate of major complications, there is now wide acceptance of use of transbronchial biopsy. The technique is applicable to diffuse lung disease both in stable patients and acutely ill patients such as the immunocompromised host. We review here the technique of fiberoptic bronchoscopy, complications, and aspects of clinical usefulness of the procedure. Our interest has been primarily in the area of diffuse and interstitial lung disease which is emphasized.

Flexible fiberoptic bronchoscopy has been a useful clinical procedure in the United States for a decade and has, in many situations, bypassed the need for rigid tube bronchoscopy.[1-3] With the advent of the ability to perform forceps lung biopsy transbronchially by way of the fiberoptic bronchoscope, the approach to the accurate diagnosis of the etiology of localized or diffuse lung disease has been revolutionized.[4] The diagnostic accuracy of this procedure may reach seventy percent.[2] The technique is relatively easy and surprisingly safe.

The purpose of this article is to discuss the methodology and the indications of transbronchial biopsy through the fiberoptic bronchoscope and to briefly discuss specific problems that may arise in assessing the biopsy specimen. Several recent articles have reviewed the general applications of fiberoptic bronchoscopy in a variety of clinical situations.[2, 4-11] When the etiology of a diffuse or localized lung lesion is still unclear after standard diagnostic procedures, fiberoptic bronchoscopy with transbronchial biopsy may be indicated to attempt to establish or rule out a specific diagnosis without resorting to open lung biopsy.

The selection and preparation of patients and technique of bronchoscopy and biopsy have been well described by Zavola.[2]

Fiberoptic bronchoscopy and transbronchial biopsy are hazardous in the uncooperative patient, in those with a significant bleeding diathesis (immunocompromised patients with thrombocytopenia may require pre-bronchoscopy platelet transfusions), and in patients with severe hypoxia or unstable cardiac status. Even patients with moderate or mild hypoxia or diminished pulmonary reserve are at substantial risk during and after the procedure.[12] Thus arterial blood gas determinations are essential prior to bronchoscopy, and almost all patients should receive supplemental oxygen during and after the procedure. Occasionally, endotracheal intubation prior to bronchoscopy is necessary. Other routine pre-bronchoscopic studies include a prothrombin time, partial thromboplastin time, assessment of circulating platelets, hemoglobin, and electrocardiogram. Pulmonary function studies may be indicated.

After inspection of the mouth, nose, and upper airways, local anesthesia is accomplished with lidocaine spray applied to the oral, pharyngeal, and nasal mucosa. Most patients also require a very mild sedative drug (e.g., codeine, 30-60 mg I.M.) and atropine prior to the procedure. The bronchoscope is carefully advanced through one nostril to above the vocal cords where a small amount of lidocaine is injected through

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the open channel of the bronchoscope onto the cords. The bronchoscope is again advanced along tracheal and bronchial airways. After inspection of all segmental and as many as possible of the subsegmental airways, various diagnostic procedures may be undertaken. These include bronchial lavage, endobronchial forceps or brush biopsy and transbronchial lung biopsy. The latter is best accomplished with the use of fluoroscopy to guide the forceps to the area of interest and to avoid the complication of pneumothorax. The biopsy forceps are passed (closed) via the open (or suction) channel of the bronchoscope after the tip of the bronchoscope is firmly seated in the subsegmental bronchus of interest. Then the forceps are advanced into the lung parenchyma, opened during inspiration, and closed while the patient is breath-holding in the expiratory phase. During this phase of the procedure the position of the forceps relative to the lesion and the pleura is constantly assessed fluoroscopically. The forceps are carefully withdrawn with attention to the possibility of intrabronchial hemorrhage.

The tissue is gently teased with a needle point out of the forceps jaws into formalin or other fixation or culture media. Prior to this step, if required, multiple imprints of tissue against clean glass slides can be made. Such slides can be later stained for cytological studies or with a variety of histochemical techniques for the demonstration of organisms. The latter procedure is of particular value in the rapid diagnosis of opportunistic infection in the immunocompromised host. A post-bronchoscopy chest radiograph should be obtained to rule out pneumothorax. Three to four biopsy specimens are usually adequate although more may be taken with apparently little risk of increased morbidity. The advantage of taking multiple biopsies is that separate pieces of lung tissue may be examined by light and electron microscopy which require different fixation techniques. In addition, separate specimens are required for bacteriology (routine and anaerobic), viral, mycobacterial and fungal cultures if indicated. We have been able to perform quite satisfactory immunofluorescent antibody studies on lung tissue obtained at fiberoptic bronchoscopy. Such studies are indicated in the workup of pulmonary hemorrhage or pulmonary-renal syndromes. Multiple tissue specimens studied by routine diagnostic microscopy helps to improve diagnostic yield and helps to eliminate sampling error as the size range of lung tissue obtained at fiberoptic bronchoscopy is usually one to three millimeters.

Fiberoptic bronchoscopy to date has proven to be a safe procedure. A retrospective survey by questionnaire reviewed complications in 24,521 procedures.[13] Three deaths were reported for an overall mortality rate of 0.01 percent. Death was attributed to cardiac arrest or cardiovascular collapse in all three, but one death was considered an adverse reaction to local anesthetic used before and during the procedure. The major complication rate was 0.08 percent. In order of frequency, major complications included respiratory depression or arrest secondary to premedication or anesthetic agent, respiratory embarrassment related to the procedure, and cardiac arrhythmias. Bronchospasm, pneumonia, pneumothorax and hemorrhage were also causes of major complications and equal in incidence. Interestingly, most major complications and all deaths were related to the inherent risks of medicating a sick patient in order to perform a procedure, and then further compromising the patient with respiratory disease by occluding airways with a bronchoscope. It is reassuring to note that in this large series, the risk of transbronchial biopsy as an additional procedure was not great, and that reported were only two major complications secondary to hemorrhage and two major complications secondary to pneumothorax. A twenty-fold and ten-fold increase in morbidity and mortality respectively were reported in a prospective study.[14] Major complications occurred in 1.7 percent of 908 patients and included cardiac arrest, pneumonia, pneumothorax and airways obstruction. One death was reported secondary to cardiac arrest. The overall incidence of pneumothorax following transbronchial biopsy was five percent. Complications considered as minor were syncope, fever, transient cardiac arrhythmias, lung bleeding, pneumonthorax, aphonia, and temporary psyhosis and were present in 6.5 percent of cases. Another study reported twelve deaths following 48,000 procedures. Eight deaths were due to cardiac arrest and five patients had a proven (autopsy) or suspected myocardial infarct.[15] These studies collectively indicate that the risk of death from the procedure is small and primarily related to hypoxemia leading to cardiac arrest or myocardial infarction. There is a smaller risk of fatal pulmonary hemorrhage. Careful selection and preoperative protection of patients selected for bronchoscopy with biopsy may decrease risk of major catastrophic bleeding, particularly in the immunosuppressed group of patients with coagulation abnormalities.

Fiberoptic bronchoscopy has proved to be efficacious for a wide variety of pulmonary diseases and conditions. Our experience has been primarily with the diagnosis of diffuse lung disease with material obtained by transbronchial (parenchymal) biopsy and that experience is emphasized below. Certainly the technique has been valuable to chest physicians, otolaryngologists, and thoracic surgeons alike and in many instances has replaced rigid tube bronchoscopy. Recent chest disease literature abounds with articles documenting the effect this instrument has had upon this field. There is now ample evidence that the fiberscope with forceps and suction channels is of immense value in clearing obstructed airways whether the lesion be an inhaled foreign body or inspissated mucous as with the post-operative or asthmatic patient.[16] [17] [18] Occasionally non-malignant disease which may have lesions distributed both in the parenchyma and in the submucosa of large airways may be diagnosed by endobronchial biopsy alone. For example, an experienced bronchoscopist may discern small, yellow-white nodules or granules along walls of airways in patients suspected of having pulmonary sarcoidosis.[11] Endobronchial biopsy of such lesions will usually yield the epithelioid granuloma characteristic of sarcoidosis. Other diseases which may be similarly and successfully approached include tuberculosis, amyloidosis, and submucosal extension of metastatic or primary malignancies; small cell undifferentiated carcinoma of lung characteristically infiltrates submucosally along airways. Perhaps the facility of diagnosis of endobronchial tumors with the fiberscope should be emphasized. The great advantage of the technique is that the entire tracheobronchial tree down to the level of subsegmental bronchi can be adequately inspected. Brushing or biopsy can be easily performed with a high rate of diagnostic accuracy.[19] Endobronchial tumor beyond the visual range of the fiberscope can not be diagnosed as readily as visible tumor but specific diagnoses can still be obtained in a high percentage of cases, therefore obviating thoracotomy. Lobar, segmental, or focally discrete lesions of pulmonary parenchyma may be biopsied with forceps and catheter tip under fluoroscopic visualization. When lesions are radiographically discrete, tumor is the usual clinical diagnosis. Fiberoptic bronchoscopy with transbronchial biopsy may yield both a specific histological diagnosis and provide some information as to extent and nature of spread of tumor within the lung and perhaps even aid in staging if there is evidence of carinal or paratracheal lymph node involvement. One author has expressed disappointment with the success rate of diagnosing parenchymal discrete carcinomas with transbronchial biopsy, 17 percent in that series.[20] He felt that in many instances biopsy forceps glanced away from relatively firm tumor masses and that negative tissue samples were obtained. He suggested that higher results might be obtained by taking multiple samples at the margin of the neoplasm thereby hoping to obtain tumor tentacles infiltrating into lung parenchyma around the edge of the tumor. Also emphasized for the pathologist was the importance of examining multiple sections of tissue from each biopsy sample received in the laboratory.

Prior to discussion of uses of the fiberscope with transbronchial biopsy in diffuse lung disease, a word need be said about the nature of the specimens obtained and the diagnostic limitations of the material. The descriptive term diffuse implies that anatomic and radiographic involvement is throughout all lung zones and that a characteristic set of physiologic parameters are altered suggesting compromise of many functional units of lung tissue. However, this does not imply that all alveoli, all interstitial structures, or even each acinus is involved in the diffuse interstitial lung diseases. Anatomically, patchy involvement is the rule in interstitial lung disease so that from one low power microscopic field to the next, tissue changes may vary from normal to severely diseased. With some diseases, such as idiopathic interstitial fibrosis, this same variation may take place but on a macroscopic basis. Therefore the risk of sampling error is great when attempting to make specific diagnoses on small pieces of tissue. Indeed, we have at times invoked sampling error, or more frequently, error in sampling, when a large segment of lung tissue obtained at open lung biopsy is not diagnostic. The quality of biopsy specimens from transbronchial biopsy has improved since initiation of the procedure in our hospital. Initially many procedures which attempted to biopsy lung parenchyma were successful in obtaining superficial bronchial mucosa or a portion of the wall, usually smooth muscle and cartilage. This material was usually non-diagnostic and probably resulted from failure to advance the biopsy forceps well past the tip of the bronchoscope and well into peripheral parenchyma. As we have become more comfortable with the indications for the performing and the actual doing of the procedure, two things have happened. First, we have gained technical expertise so that, depending upon the question being asked, the tissue biopsy is usually from the correct lesion, i.e. mass, wall of airway, alveolar parenchyma, so that at least an approach to diagnosis can be made. Importantly, this also spares the patient a second bronchoscopy or the open lung biopsy. Secondly, as we have become more comfortable with the infrequency of major complications and have accepted the risk of the many minor complications, bronchoscopists are taking many more biopsy specimens, greatly increasing total amount of tissue that can be studied microscopically and thus increasing the diagnostic yield. The size of individual samples ranges from one to three millimeters. One margin of each sample, ranging from one-third to one-fourth of the surface area is not interpretable due to artefact secondary to crush by the biopsy forceps. If the specimen has been handled gently prior to fixation, the remainder of the tissue may be well preserved and quite adequate for diagnostic interpretation. When the tissue consists of mostly distal airways as many as twenty alveoli and adjacent supporting structures may be seen in the best biopsies. One of our initial observations was that a surprising number of biopsies contained portions of small to medium sized thin walled vessels and adjacent connective tissue sheath and surrounding alveoli. These structures represented a portion of interlobular septum with pulmonary vein. No doubt as the forceps tip was advanced, these relatively tough and elastic structures were pushed before it but not penetrated so that the septum was biopsied when the forceps jaws were open and shut. Surprisingly perhaps, significant hemorrhage has not resulted from such biopsies. In summary, multiple biopsies from the most desired anatomic location we feel has greatly increased our abilities to approach the diagnosis of diffuse lung disease with the transbronchial biopsy.

In an early large review, Zavala studied with fiberoptic bronchoscopy and biopsy, 221 patients with non-malignant chest disease out of a total of 600 patients.[2] This work suggested that granulomatous disease including tuberculosis, nonspecific interstitial pneumonia, specific interstitial pneumonia such as radiation pneumonitis and a wide variety of infectious agents in pneumonias of immunocompromised hosts could successfully be investigated with fiberoptic bronchoscopy. A large percentage of patients with medical disease, 42 percent, were diagnosed as having bacterial pneumonia reflecting perhaps that initially biopsies were performed in some patients where more traditional methods of specimen collection might have sufficed. Interestingly, later studies indicate a reversal of the ratio of malignant disease to non-malignant disease undergoing investigation.[21] This may be due to the more widespread acceptance of uses of bronchoscopy and biopsy in distinct classes of patients such as an early approach to diagnosis and therapy in immunocompromised hosts, and that the relative benignancy of the procedure has allowed it to become almost a "routine" tool in the diagnosis and management of a wide variety of medical lung disease. Our impression and that of others in our institution is that the relative incidence of procedures performed for malignant as opposed to non-malignant diseases is about equal.[22] In one study, 19 of 22 patients studied had anatomic diagnoses which correlated with subsequent tissue diagnoses from either open lung biopsy or autopsy, positive cultures, or the clinical picture. Diagnosed were such diverse conditions as usual and desquamative interstitial pneumonia, rheumatoid lung, pulmonary alveolar proteinosis, vasculitis, lymphocytic interstitial pneumonia consistent with viral pneumonia, cytomegalovirus pneumonia, and pneumonia due to Pneumocystis carinii.[4] A larger series adds radiation fibrosis, pneumoconiosis, sarcoid, eosinophilic pneumonia, bronchiolitis obliterans among other entities to the list.[21] In passing we should mention that the latter study documents the usefulness of transbronchial biopsy in two categories of malignancy which often fall under the clinical heading of diffuse lung disease, metastatic carcinoma and alveolar cell carcinoma of lung which reflects our own experience. Overall, the diagnostic usefulness of transbronchial biopsy with diffuse lung disease ranges from 64 to 84 percent.[4 21 23] While these statistics are impressive it is worth pointing out that in all instances nonspecific histology is not of totally negative value and that many times the exclusion of certain processes or decreasing the likelihood that certain infectious agents are present contributes greatly to the subsequent management of the patient. With respect to diffuse interstitial lung disease, our experience has tended to parallel that of others in that the majority of patients biopsied have conclusions drawn which contribute to care in the form of specific diagnoses or diagnoses consistent with the clinical picture. The immunocompromised host deserves special comment as our case material is heavily weighted by this group and is discussed below. Excluding this latter group of patients, a survey of three years experience at the Yale-New Haven Hospital indicates that close to half of all remaining positive procedures performed for diffuse and non-malignant lung disease yield epithelioid granulomas which ultimately prove negative for microorganisms. Obviously most of these patients clinically have idiopathic sarcoidosis. While this unusual incidence reflects a focus on sarcoid at our hospital, it does serve to underscore the extremely high yield in diagnosing granulomatous inflammation both by bronchial and transbronchial biopsy, consistent with results reported by many authors.[11 24] Diverse diagnostic labels have been placed upon remaining patients in our series with idiopathic pulmonary fibrosis, the second most commonly seen entity. Asbestosis, amyloidosis, idiopathic pulmonary hemosiderosis, eosinophilic granuloma of lung, and chronic passive congestion secondary to heart disease have been diagnosed with the same degree of confidence as offered by the open lung biopsy.

Immunocompromised hosts are defined broadly as those patients in whom either disease or therapy for disease renders them more susceptible to infection. The patient that perhaps best typifies this group is the one with malignancy or organ transplant treated with cytotoxic agents, immunosuppressive drugs, or steroids, perhaps all three. Pneumonias in such patients may be acute or chronic, but often lead to extreme morbidity or mortality. While common bacterial pathogens are frequently encountered in immunocompromised hosts, a variety of viral, fungal, protozoan and mycobacterial infections are seen. Many studies have shown the utility of fiberoptic bronchoscopy, particularly in the early approach to diagnosis and therapy and have emphasized that the procedure including biopsy can be performed in stable or acutely ill patients with little or no increased morbidity.[5 10 21 26] Hemorrhage is a rare major complication unless coagulation disorders are present.[26] Matthay and associates reported a series from our hospital in which there was a high diagnostic yield with a specific infectious agent recognized in 56 percent of procedures, and no specific diagnosis in only 16 percent of patients. (Secondary neoplasm, hemorrhage, and radiation penumonitis were among the specific lesions diagnosed in other patients.) The most common bacterial species recognized was Klebsiella (five cases). Two of three fungal infections diagnosed were due to Aspergillus species. Nocardia infection was diagnosed in two instances. Although Pneumocystis carinii infection is infrequent at our hospital, we concur with other authors that fiberoptic bronchoscopy with both bronchial brushing and transbronchial biopsy establishes the diagnosis of this entity in a high percentage of cases. We emphasize again that negative results can be helpful in this category of patients allowing the physician to withhold potentially toxic antibiotic or chemotherapeutic agents or to focus therapy on a narrowed differential list of infectious agents. That is not to say that negative results mean absence of disease. A recent study cautions against complacency when tissue reports indicate nonspecific inflammatory changes or fibrosis.[26] The high incidence (16 of 40 procedures or 40 percent) of such changes reported notwithstanding, subsequent studies in seven patients established a specific diagnosis followed by new and directed therapy leading to improvement in the majority. In addition to infectious pneumonias, immunocompromised patients with malignancy and diffuse lung disease may harbor tumor in the lungs or may have acute interstitial penumonia secondary to drug or radiation therapy. A negative bronchoscopy with biopsy never entirely excludes the possibility of tumor but may help eliminate that possibility. While changes of drug toxicity to lung as seen with bleomycin or cyclophosphomide can be diagnostic, we admittedly have had some difficulty distinguishing among the diffuse alveolar damages of drug, viral, or other injury. Immunocompromised hosts with infection present a special challenge to a health care team of many disciplines. Fiberoptic bronchoscopy combined with various techniques for specimen collection has emerged as a valuable diagnostic modality. While there is some discrepancy in the literature as to the frequency with which a specific etiologic diagnosis is provided, there is general agreement that due to minimal risk and the possibility of sparing the patient more aggressive procedures, bronchoscopy and biopsy are indicated in the early evaluation of pulmonary infection in the immunocompromised host.

We have attempted to present an overview of fiberoptic bronchoscopy and biopsy. The flexible bronchoscope is now a standard tool for lung endoscopy. Biopsy has proven to be of minimal risk. Diagnostic yield is variable depending upon the patient population studied and interpretation of data. We hold that the great majority of biopsies provide either specific diagnoses or important negative information. This we feel is particularly true in the investigation of diffuse lung disease. From the point of view of the pathologist, the major limitations to even higher diagnostic yield are sampling error due to small size of the biopsy specimen and nonspecific inflammatory changes seen histologically. We continue to support use of this procedure in the early evaluation of pneumonia in the immunocompromised host.

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Recent Advances in Diagnostic Pathology of the Gastrointestinal Tract

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The recent decade has produced significant progress in our understanding of gastrointestinal diseases and in our ability to diagnose them. Advances have been made in the recognition of certain conditions that predispose to malignancy and in technical innovations that have increased the precision of the diagnostic process. Improved diagnostic sensitivity has allowed earlier treatment of certain malignancies with consequent improvement in prognosis. This review will concern itself with selected topics of recent interest in the area of gastrointestinal neoplastic disease and its diagnosis.

I. Endoscopy: State of the Art

The introduction of the fiberoptic endoscope by Hirschowitz et al in 1958[1] heralded a new era of diagnostic precision in gastrointestinal disease. The esophagus, stomach, duodenum and colon, as well as the pancreatic and biliary tree may now be evaluated. In addition to the improved visibility afforded by the modern flexible endoscope with its excellent optics and easy maneuverability, various techniques for accurate mucosal sampling under direct vision have been devised. Precisely localized punch biopsies may be obtained and material for cytological examination may be collected by directed brushings, selective lavage and aspiration.[2]

Liebermann and Barnes recently reviewed the various indications for diagnostic gastrointestinal fiberoptic endoscopy as well as certain aspects of therapeutic employment.[3] Esophageal symptoms frequently require endoscopic investigation for follow-up of radiographic abnormalities, primary diagnosis, or therapy. Directed biopsies can diagnose in excess of 80% of malignant lesions. The addition of brush cytology has raised the level of accuracy to more than 95% and even 100% in some series.[4 5 6 7] Esophagitis may be recognized and specific infections, such as the monilial and herpetic lesions found in immunocompromised patients can be identified by biopsy and brushings for cytologic and cultural studies.[8 9] Newly diagnosed cases of achalasia should be evaluated endoscopically to exclude an infiltrating gastric malignancy.[3]

Although classical duodenal ulcer disease does not ordinarily require endoscopy, this form of investigation should be used in the evaluation of gastric ulcers, especially those which appear malignant or indeterminate.[3] Evaluation is based upon gross appearance, supplemented by multiple biopsies of the ulcer margin and direct brushings for cytologic study.[10]

Recent series have reported high levels of accuracy in the diagnosis of gastric malignancy using a combination of biopsy and brush cytologic techniques. Thompson et al[11] in a series of 59 cases achieved 90% accuracy with brush cytology compared with 76% on histology; the combination of the two methods gave an accuracy of 98%. A similar study by Halter et al[12] achieved 84% accuracy with cytology and 86% from histology with a cumulative accuracy of 96%. Other studies showed an appreciable increase in accuracy for cytology (94%[13] and 69%[14]). No false positive results were reported in these two series. This high degree of specificity should indicate rigorous investigation of any patient with an apparent false-positive cytologic diagnosis, as the cytologic evidence may precede other findings in gastric carcinoma.[15] Recent series of gastric lymphoma cases give a cytologic accuracy of 70 to 88 percent.[16 17 18 19]

Endoscopic evaluation of chronic upper gastrointestinal bleeding may confirm radiographically demonstrated disease or detect lesions not found radiographically. Esophagogastroduodenoscopy is more accurate than conventional radiographic examination in acute gastrointestinal bleeding caused by esophageal varices, gastric ulcer or duodenal ulcer.[20] Endoscopy may be the only technique to identify erosive gastritis

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or Mallory-Weiss lacerations.[3] Endoscopy may be useful in defining the site(s) of bleeding prior to emergency surgery, permitting the surgeon to perform selective rather than blind gastric resections.

Endoscopic studies may help in the evaluation of certain post-gastrectomy syndromes, for in some instances surgical distortion may make post-operative radiographic evaluation quite difficult or even impossible. Thus, stomatitis, gastritis and marginal ulcers may often be seen only by endoscopic means.[3] Hirschowitz and Luketic[21] recommended endoscopic evaluation of patients with post-gastrectomy complaints, especially those suggesting mechanical or functional defects.

Upper gastrointestinal endoscopy has also found employment in certain therapeutic situations, such as removal of foreign bodies from the esophagus or stomach, gastric polypectomy, direction of guidewires for Eder-Puestow dilators in benign and malignant strictures of the esophagus, and insertion of Celestin or other esophageal prostheses.[3] Techniques under investigation for control of upper gastrointestinal bleeding include use of the Argon and Neodinium-YAG laser,[22] the heater probe, and electrocautery.

Endoscopic retrograde cholangiopancreatography (ERCP) has recently emerged as an extremely useful technique for opacifying the pancreatic and/or biliary tree. In the hands of skilled operators, success has been reported in cannulating 90 to 95 percent of pancreatic ducts and 80 to 85 percent of common bile ducts.[5 23 24] Unfortunately, the procedure carries some risk; in over 8,000 examinations, complications occurred in 3% and death in 0.2% of patients.[25] Sepsis due to pancreatitis or cholangitis was the major complication. ERCP is useful in the evaluation of strictures of the biliary tract, benign and malignant. The technique may be used as a supplement or alternative to percutaneous transhepatic cholangiography in patients with obstructive jaundice, especially in cases where the ducts are not dilated.[3] Therapeutically, endoscopic papillotomy has been utilized in patients with retained calculi in the common bile duct.[6] Seven days following papillotomy, ERCP is performed. If the stone(s) is still present, the incision may be enlarged or the operator may attempt to remove it with a balloon catheter or Dormia basket. In a recent series of 1,100 cases, 63% of patients passed the stones spontaneously following endoscopic papillotomy. The stones could be extracted by instrumental techniques in an additional 26%. Unfortunately, this procedure is also associated with significant complications including pancreatitis, perforation, bleeding, cholangitis, and sepsis (8.5% of 1,107 cases). The complications were related to impaction of the calculi in the distal common bile duct with consequent ascending infection. The mortality rate is quoted as between 1 and 2 percent.[26]

ERCP has been of use in the preoperative assessment of patients with chronic relapsing pancreatitis for the identification of strictures as well as pseudocysts. The postoperative evaluation of drainage procedures may also be accomplished.[27]

The fiberoptic colonoscope may be employed in the inspection of the entire colon. This procedure is used in complementary fashion with diagnostic radiography. Some authors have reported an increased yield of colonic polyps using colonoscopy in addition to barium radiography,[28] while others have pointed out frequent cases of polyps detected radiographically which were missed on colonoscopy.[29] The procedure has been used in patients with carcinoma to detect synchronous polyps or malignancy.[30] The differential diagnosis of colonic strictures in patients with diverticular disease has been improved by colonoscopic investigation.[31] Strictures occurring in inflammatory bowel disease may also be evaluated.[32] Pancolonoscopy may be of significant value in the study of patients with chronic rectal bleeding, especially those with negative radiographic studies.[33] Aside from carcinoma, polyps, diverticular and inflammatory bowel disease, angiodysplasia may be recognized as a source of recurrent bleeding.[34]

Therapeutically, colonoscopy is now utilized extensively for polypectomy. The procedure is most useful for pedunculated polyps; some sessile polyps may also be removed safely. The most common complications are bleeding and perforation.[35]

II. Barrett's Esophagus and Esophageal Adenocarcinoma

Many patients with sustained gastroesophageal reflux develop chronic esophagitis which may progress and become complicated by peptic ulceration and stenosis. During this process, the normal squamous epithelial mucosa may become converted into a columnar lining. In 1950, Barrett[36] described the syndrome now usually identified with his name and suggested that the columnar epithelium lined an intrathoracic stomach in patients with a congenitally short esophagus. However, most authors now feel that the intrathoracic columnar epithelium is acquired as a result of metaplastic upward extension of the non-acid-secreting columnar epithelium of the proximal normal cardia.[37] In patients with this condition, manometric studies have shown that the motor function of this segment resembles that of the esophagus and the lower esophageal sphincter occurs distal to the columnar-epithelial-lined segment.[38 39]

Observers have differed considerably in their descriptions of the histologic features of the columnar lining. The epithelium has been characterized as gastric fundic,[40 41] junctional,[39] intestinal,[41] or as a unique type of specialized columnar epithelium which contains goblet cells but still is unlike other alimentary epithelia.[42 43] Pauli and his co-workers demonstrated a spectrum of epithelial patterns: atrophic gastric-fundic-type epithelium with parietal and chief cells, junctional-type epithelium with cardiac mucous glands, and distinctive, specialized columnar epithelium with a villiform surface, mucous glands, and intestinal-type goblet cells.[44] In a detailed study using light and electron-microscopy, Ozzello et al[37] also recognized a heterogeneous cell population of normal parietal, chief, Paneth, goblet and endocrine cells as well as other cells which had only some features in common with known gastric or intestinal cells and displayed or lacked other features which made them appear quite different. They were struck by the varying degrees of architectural complexity ranging from simple columnar epithelium to glands containing highly differentiated cells. This mucosa could be characterized by gastric intestinal and unclassified features; it was thought to be pathologic and *sui generis* in that it has no equivalent in the normal and abnormal gastrointestinal tract. These workers felt that the progenitor cells that give rise to such metaplastic and peculiar epithelium might be undifferentiated foregut cells capable of mimicking in the course of their evolution various types of gastrointestinal cells without necessarily reaching full maturity.

In recent years, a number of investigators have recognized an association between Barrett's esophagus and primary esophageal adenocarcinoma. The strength of this association has been confirmed and it is postulated that columnar epithelium lining the esophagus represents a premalignant condition.[45-50] Naef and co-workers[51] found 21 patients with esophageal adenocarcinoma in a series of 140 patients with Barrett's esophagus; they considered this 8.5 percent prevalence sufficient evidence to implicate a causal relationship. In a review of 14 cases of primary esophageal adenocarcinoma, Haggitt et al[52] found that 12 (80%) arose in a Barrett's esophagus. Microscopic examination revealed a spectrum of abnormalities that ranged from mild dysplasia to carcinoma-in-situ in the columnar epithelium adjacent to and remote from the invasive adenocarcinoma. If a dysplastic stage precedes the invasive malignancy, as the strong association between the two suggests, repeated endoscopic biopsies and cytologic examinations at regular intervals might offer effective means for monitoring the onset of a premalignant phase in the columnar-lined epithelium.[53] Although correction of gastroesophageal reflux by fundoplication relieves symptoms, the columnar lining apparently does not regress,[54] nor is the predisposition to malignancy prevented.[51] Indeed, in two of the patients reported by Haggitt and co-workers,[52] carcinoma developed in the columnar epithelium-lined esophagus three and three and a half years after fundoplication, supporting the contention that antireflux surgical treatment fails to prevent malignancy.

III. Early Gastric Carcinoma

Renewed interest in gastric carcinoma started in Japan in the early 1960's. With a death rate from gastric carcinoma of about eight times that of the United States,[55] the Japanese started a mass screening program using mobile x-ray units.[56] While the overall standardized death rate from gastric carcinoma dropped over the screening period, the drop appeared to be independent of the local examination rates, leading Kawai[56] to assume that there was little direct effect on the death rate. Nevertheless, the program provided a wealth of clinical material leading to a much clearer understanding of the natural history of early gastric carcinoma.

The Japanese screening detected increasing numbers of cases with so-called early gastric cancer, defined as being limited to the mucosa or submucosa. When resected, this lesion was found to have an excellent prognosis with five year survival rates of over 90%.[58] In 1962, the Japanese Gastroenterological Endoscopy Society[58] formulated a standardized nomenclature for early carcinoma which included three types: Type I: Protruded (or polypoid); Type II: Superficial, with elevated (a) flat (b), and depressed (c); and Type III: Excavated. Any particular lesion usually shows a combination of types with II-c and II-c plus III being the most common. The lesions tend to be located along the lesser curvature and, in 24% of one series of cases,[59] were multiple.

When the lesion is limited to the mucosa, metastasis is rare; but, when the submucosa is involved, metastases were found in 12%. Even so, the five year survival rate was still 93%.[57] While it has been suggested that gastric carcinoma in Japan may be biologically different from that encountered in western countries,[61] studies in Britain[59] and Germany[60] have demonstrated entirely similar lesions to those described in the Japanese literature. Thus, the relative ease of gastric endoscopy with biopsy and brush cytology,[62] sophisticated radiographic techniques, i.e. double contrast barium study, and even improved cytologic techniques, such as chymotrypsin lavage, offer the possibility of detecting early potentially curable lesions.[63] Because a family history of gastric cancer, pernicious anemia, hypertrophic gastritis, prior gastrectomy, smoking, alcoholism, gastric polyps, and gastric ulcer disease have all been reported to increase the risk of developing gastric carcinoma, their presence should alert the clinician to search for early gastric lesions.

IV. Pancreatic Carcinoma

Carcinoma of the pancreas remains a very discouraging problem with a five year survival of less than 1%,[65] and a disturbing increase in incidence.[55] Because tumors of the head of the pancreas, which may present early with obstructive jaundice, tend to have a somewhat better prognosis than tumors of the tail, there is some hope that early diagnosis may improve the grim prognosis.[66] Indeed, rare patients with small asymptomatic lesions found incidentally have done well after resection, supporting this concept.[67] Although a variety of sophisticated diagnostic techniques[68] are now available, the fact that symptoms tend only late in the course of the disease, often leads to diagnosis of advanced and inoperable lesions. Routine laboratory studies including measurements of carcinoembryonic antigen, alpha fetoprotein, and pancreatic oncofetalantigens as well as radionucleotide scans have been of no help in detecting early lesions.[67 69]

The mainstays of current diagnosis include pancreatic ultrasonography with reported diagnostic accuracies of 67 to 91 percent,[68-71] computed tomography (CT) with an 80 to 94 percent accuracy,[69 72] and retrograde cholangiopancreatography (ERCP) with a 73 to 88 percent accuracy.[69 70]

An interesting development is the use of ERCP to obtain aspiration and brush cytology specimens from the pancreatic duct with a reported positive or suspicious rate of up to 90%.[73] Duodenal drainage procedures following secretin administration have also yielded cellular samples.[74] The procedure has the advantage of not requiring ERCP and in some hands has produced a 78% positive or suspicious rate for cases later diagnosed as cancer. Unfortunately, other investigators[69] have only been able to find cancer in 14% of their cases.

There has also been a great deal of interest in percutaneous biopsy techniques using fine 20-23 gauge needles guided by ultrasound, angiography, computed tomography, or ERCP. A variety of authors have reported accuracies in the range of 67 to 90 percent[75-78] with this technique.

Despite these considerable advances, the problem of detection in asymptomatic patients persists. Although unavailable now, what is sorely needed is a screening technique to detect earlier lesions than are now being found, for at present 90% of all cases are inoperable when diagnosed.

V. Carcinoma of the Colon

Despite contrary views,[82-84] there is good evidence that many, if not most adenocarcinoma, arise in epithelial polyps,[85 86] especially the larger (greater than 1.5 cm) adenomas with villous features.[87] While the process of malignant transformation may take from five to thirty years to occur,[85] it is probably not inevitable. The absence of lymphatics in the mucosal lamina propria[86] explains the rarity of metastasis in lesions that do not penetrate the muscularis mucosae. It is therefore important to detect and remove these adenomas early in their course. The combined use of contrast roentgenography and colonoscopy have been shown to improve the detection of polyps.[28 79] Barium enema examination alone, while successful in identifying more than 90% of Dukes' C and D carcinomas, in one study[80] failed to detect 19 of 45 Dukes' A and B lesions.

Colonoscopic directed biopsies have been reported to have a positive yield of 71% in exophytic cancers and 33% in infiltrating lesions.[81] The addition of brush cytology increased the yield to 94% for exophytic and 78% for unfiltative lesions, suggesting that it may be an important adjunct to biopsy.

Chronic ulcerative colitis presents a different problem. Since 1967,[88] it has been observed that colon carcinoma, while increased in frequency in ulcerative colitis, does not arise in the usual polyp-cancer sequence. Rather, epithelial dysplasia appears which is interpreted as a precancerous lesion. In one review,[89] 19% of patients with colitis of 10 or more years duration had precancer on rectal biopsy. One third of the patients with precancer were also found to have colonic carcinoma. Thus, while the lesion is not a specific marker for the presence of cancer, it is of value in that it identifies a higher-risk sub-group. Since precancer was absent in 12% of the patients with carcinoma, a negative finding is of no value. Nevertheless, colonscopy in patients with colitis[90] allows the physician to sample any unusual lesion detected on x-ray studies or seen in the course of periodic examination.

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The Art of Medicine

Emulating the persistence and care of Darwin, we must collect facts with open-minded watchfulness, unbiased by crotchets or notions; fact on fact, instance on instance, experiment on experiment, facts which fitly joined together by some master who grasps the idea of their relationship may establish a general principle. But in the practice of medicine, where our strength should be lies our great weakness. Our study is man, as the subject of accidents or diseases. Were he always, inside and outside, cast in the same mould, instead of differing from his fellow man as much in constitution and in his reaction to stimulus as in feature, we should ere this have reached some settled principles in our art. And not only are the reactions themselves variable, but we, the doctors, are so fallible, ever beset with the common and fatal facility of reaching conclusions from superficial observations, and constantly misled by the ease with which our minds fall into the ruts of one or two experiences.

—William Osler, *Teacher and Student,* on address to medical undergraduates at the University of Minnesota, 1892.

The Contribution of Electron Microscopy to Diagnosis in Pathology

MICHAEL KASHGARIAN, M.D.

At the time of the last review of the subject in this journal,[1] electron microscopy was still a highly specialized technique which was extremely difficult to apply in routine fashion because of the extraordinary care, effort and expense involved in the functioning of the electron microscope. The reliability of the instruments of that day was extremely variable. The vagaries of processing were not controlled or standardized and the product was frequently distorted by numerous artifacts.

Within the past ten years the technology involved in electron microscopy has advanced so rapidly that it can now be considered a routine pathological technique. Modern electronics has made the instrument of today stable, reliable and so simple to use that an inexperienced operator can learn to use the microscope effectively with as little as one hour of instruction. Even the simplest and least expensive of modern instruments far surpasses the capabilities of the most sophisticated instrument available 15 years ago. These technological advances have made it possible for any major general pathology laboratory to maintain and utilize the electron microscope without concern about difficulty of techniques or maintenance since any senior medical technologist can be quite capable of performing all of the functions associated with diagnostic electron microscopy.

Fifteen years ago the application of electron microscopy to medical diagnosis was limited to extremely rare instances and for highly specialized tasks such as the identification of viral particles.[1] Its chief utility appeared to remain with the field of basic investigative morphology. The utilization of ultrastructural examination of renal tissues was just beginning and sufficient information had not yet been gathered to justify its routine application.

At the present time, while gross examination and light microscopic examination of tissues still remains the standard diagnostic method of diagnostic pathology, electron microscopy is now utilized in a routine fashion to contribute to the precise interpretation and clarification of difficult diagnostic problems in a variety of fields. The value of electron microscopy in the study of renal biopsies is so well established that an adequate diagnosis cannot be made in the absence of ultrastructural examination.[2] Similar utilization of the electron microscope is also growing in the interpretation of other diagnostic biopsies, such as skin, liver,[3] bowel and muscle biopsies. The greatest recent progress has been in the application of electron microscopy for accurate diagnosis of neoplastic processes.[4]

Some of the problems which have inhibited greater utilization of ultrastructural examination and diagnostic pathology have been the mistaken belief that tissues fixed in the conventional manner would be unsuitable for ultrastructural study and that processing took 2-3 weeks before information became available. While the utilization of specialized fixation techniques certainly enhances the quality of electron micrographs tissue specimens fixed in formaldehyde and even after embedding in paraffin can be retrieved and reprocessed for electron microscopy with excellent results. These techniques are now utilized routinely in our laboratory and have provided answers in diagnoses which would otherwise not have been available. Furthermore, processing to the point of interpretation takes only 2 or 3 days making the information available in a clinically useful time period.

The purpose of these introductory remarks are to emphasize that routine diagnostic electron microscopy has matured and has an important role in modern medical care. Because considerable expense and special training are still needed, it is unlikely that every community hospital can adequately justify its own electron microscope laboratory at the present time. This should not restrict the utilization of this technique

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however, since at least four diagnostic electron microscopy laboratories are presently functioning in the State of Connecticut and are acting as regional resources. These include the Department of Pathology at the University of Connecticut Health Center, the Hartford Hospital, the West Haven Veterans Administration Hospital and our own here at the Department of Pathology of the Yale University School of Medicine. Pathologists in all of the laboratories are available for consultation and assistance in the diagnosis of difficult cases where electron microscopy will be of help. Finally, electron microscopy is recognized by third party payers as being a necessary and routine pathological method and as such is reimbursable through their mechanisms.

As an indication of the degree of applicability of this technique a recent study by the Veterans Administration[5] has demonstrated that electron microscopy made a significant contribution to somewhere from 4 to 8% of all surgical specimens examined. In our own laboratory approximately 4% of all specimens subjected to light microscopic examination also receive ultrastructural study. In my own opinion as experience with this technique continues to grow, ultrastructural examination will be a necessary adjunct for pathological diagnosis in as high as 10% of all cases.

Perhaps the greatest contribution of electron microscopy diagnosis in pathology is in the area of the evaluation of the renal biopsy. Electron microscopy has contributed so much to the classification of renal disease that it is now essential that all renal biopsies be examined by electron microscopy as well as by light and immunofluorescent microscopy. Ultrastructural examination allows us to localize immune complexes and to better interpret changes in glomerular cellularity, basement membranes and epithelial cell morphology necessary for exact diagnosis. It is particularly useful in the evaluation of patients with the nephrotic syndrome, proteinuria of unknown etiology, various forms of acute glomerular disease, systemic vasculitities and in the evaluation of transplant success or failure. The information obtained by electron microscopy has allowed for a classification on the basis of the ultrastructural findings and the separation of a variety of disease entities with the same clinical presentation into individual categories with significant therapeutic and prognostic significance.

For example, in the evaluation of the primary nephrotic syndrome the histopathology of renal biopsies can be quite varied. In Table I a rough subcategorization is based on the presence or absence of cellular proliferation. Yet, it can be seen that that categorization becomes even more complex when electron microscopic findings are assessed. Such a categorization would be relatively unimportant unless there is a specific clinical correlation which would justify such a subdivision. Indeed in the assessment of so-called "Lipoid" it can be seen that there are at least three subcategories and recent work from our own[6] and other groups has demonstrated that a predicted response to therapy and prognosis is related to the ultrastructural findings. For example, pure minimal change disease without evidence of glomerular sclerosis has a high degree of responsiveness to steroid therapy. In contrast, while steroids do not appear to be of significant value in inducing a remission in membranous nephropathy they have been implicated recently as being important modifiers of the natural history of the disease.[7]

While the utilization of electron microscopy in the diagnosis of highly specialized areas such as renal disease is now well established, the greatest growth area for utilization of this technique appears to be in the realm of tumor diagnosis. Many tumors are so poorly differentiated that a specific histologic type cannot be assigned with any degree of certainty by light microscopic criteria alone. In other instances the similarity of light microscopic characteristics make it difficult or

Table I
RENAL GLOMERULAR LESIONS IN NEPHROTIC SYNDROME

	Light Microscopy	*Electron Microscopy*
Lipoid Nephrosis		
Minimal Change (Lipoid Nephrosis)	no lesion	foot process fusion
Focal and Segmental Sclerosis	focal glomerular sclerotic lesions	foot process fusion
Mild Proliferative Glomerulonephritis	mild mesangial proliferation	mesangial sclerosis and deposits
Membranous Glomerulopathy	membrane thickening	epimembranous deposits
Diabetic Glomerulopathy	membrane thickening lobular sclerosis	no deposits uniform membrane thickening
Amyloid	glomerular hyalinization	amyloid fibrils
Proliferative Glomerulonephritis		
Membranoproliferative Glomerulonephritis	lobular proliferation	subendothelial deposits, or intramembranous dense deposit, or dissolution of basement membrane
Proliferative Glomerulonephritis	mesangial proliferation	mesangial deposits and/or subepithelial "humps"

sometimes impossible to separate out one tumor type from another. A variety of ultrastructural features of cells have proven to be important diagnostically in identifying and classifying neoplasms. The presence of desmosomes (Figure 1) and specialized intercellular junctions are helpful in distinguishing epithelial tumors from mesenchymal tumors. The presence of basal lamina, microvilli, tonofilaments, cytoplasmic filaments of various sizes in a specific pattern of arrangement or relationships to other structures, secretory granules, melanosomes or premelanosomes, glycogen particles, crystals, nuclear alterations, neurofilaments, lipid granules and alterations in endoplasmic reticulum all have proven valuable in separating out one tumor type from another. Again the value of this categorization is only as important as its clinical usefulness. In present day oncology numerous protocols have been developed for the treatment of specific tumors with radiation and chemotherapy and making it even more imperative for accurate classification. Ultrastructure has proven to be of a special importance in the categorization of undifferentiated malignant tumors, soft tissue tumors, endocrine tumors, and of considerable value in analyzing neoplasms of the lymphoreticular and hemopoetic tissues.

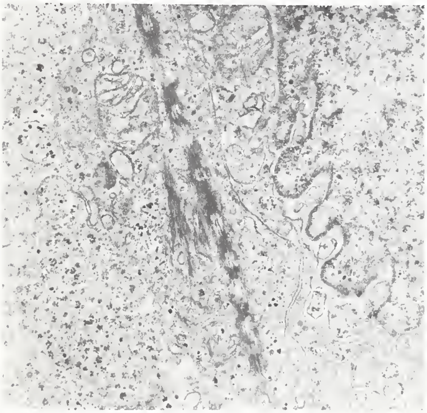

Figure 1
Electron micrograph of intercellular region of two cells in a poorly differentiated malignant tumor. There are numerous desmosomes and tonofilaments consistent with a poorly differentiated squamous carcinoma.

As an example, the pattern of a small round cell tumor of childhood can be compatible with neuroblastoma, Wilm's tumor, Ewing's sarcoma, embryonal rhabdomyosarcoma, malignant lymphoma or leukemic infiltration. Neuroblastoma can be differentiated by the identification of dense core granules that represent neurosecretory granules. Ewing's sarcoma on the other hand should have abundant amounts of glycogen. In Wilm's tumor ultrastructural examination will demonstrate primitive epithelial cells displaying junctional complexes (Figure 2). Finally, the absence of specific intercellular junctions or cellular organelles and a nucleus typical of the lymphoid series will help to distinguish lymphoreticular and hemopoetic tumors from epithelial or mesenchymal neoplasms (Figure 3).

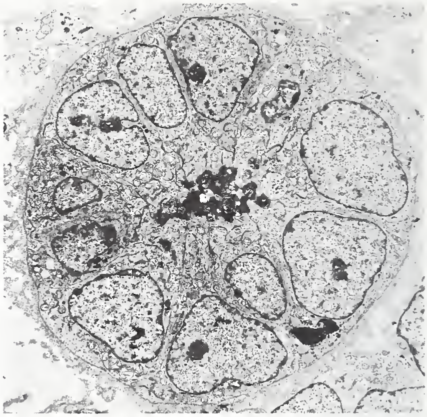

Figure 2
Electron micrograph showing a tubular structure of poorly differentiated cells in a Wilm's tumor.

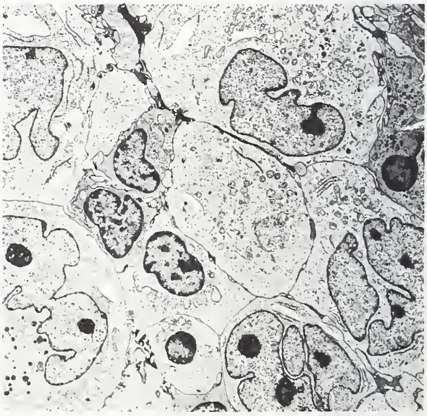

Figure 3
Electron micrograph demonstrating a mixed undifferentiated cell population with large cells with the convoluted nuclei of Reed Sternberg cells.

For years soft tissue tumors have been the subject of many open debates between pathologists as to specific cell type. Electron microscopy has been particularly useful in this area of diagnosis because distinct ultrastructural cytologic features easily identify one cell type from another. The identification of myofilaments and Z band material distinguishes a rhabdomyosarcoma (Figure 4) from a leiomyosarcoma where filaments of one size are present with focal dense aggregations. Synovial sarcomas usually have an abundance of intracytoplasmic microfilaments, a poorly developed endoplasmic reticulum and specialized intercellular junctions. Liposarcomas will usually demonstrate the presence of lipid in a variety of patterns in intracellular organelles. Ultrastructural examination of tumors of osteogenic origin will frequently show early mineralization of cytoplasm without the presence of obvious ossification by light microscopy. Another outgrowth of the study of soft tissue tumors has been the suggestion of a common origin of all these tumors with differentiation into a specific type being only a sign of maturation of the tumor and that they all may be interrelated.

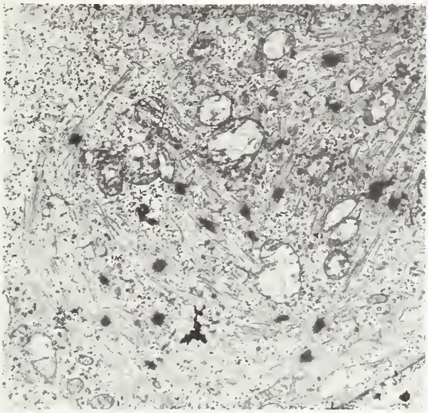

Figure 4
Electron micrograph showing poorly differentiated mesenchymal cell with numerous bundles of microfilaments and Z band material in a rhabdomyosarcoma.

The identification of specific intracellular organelles such as neurosecretory granules (Figure 5) or melanosomes or premelanosomes has also been an important tool in separating out specific tumor types. Dense core secretory granules can be of varying sizes and may help to distinguish carcinoid tumors from insulin secreting tumors and neuroendocrine tumors from epithelial tumors. The presence of melanosomes will make the diagnosis of malignant melanoma.

In summary, diagnostic electron microscopy has progressed over the past 15 years to the point where it may now be considered to be a routine diagnostic procedure. It can be easily applied to readily available material including material fixed in formalin or embedded in paraffin. It has demonstrated specific usefulness in the interpretation of renal biopsies and is now developing greater and wider application in the field of tumor diagnosis.

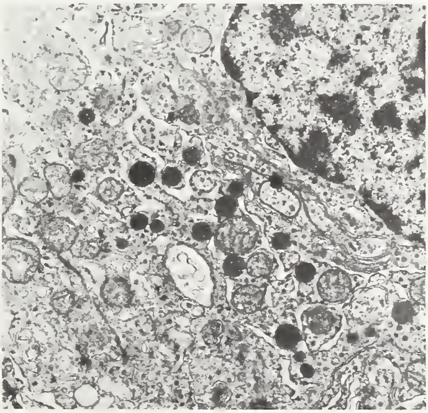

Figure 5
Electron micrograph of a poorly differentiated cell with neurosecretory granules in a patient with hypertension. These findings made a diagnosis of extra-adrenal pheochromocytoma.

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The Autopsy—A Valuable Tool in Medicine

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Introduction

Over the past 25 years, there have been numerous articles, editorials, letters and symposia in the medical literature, dealing with various aspects of the autopsy. Many of these articles have attempted to explain, evaluate and reverse the trend to decreasing numbers of autopsies on hospitalized patients.

The autopsy has different significances for different people, depending on their relationship to the patient and their role in medical care.[1] There are major benefits which accrue to the family, attending physicians, the broader medical community, law enforcement officials and society in general. In this article, I plan to concentrate mainly on the contributions the autopsy has made, and continues to make, to the practice of medicine.

Historical

The autopsy is not a new procedure. Its roots have been traced far back into history, where 3,500 years ago, the knowledge of normal and abnormal anatomy resulted from attempts to foretell the future by examination of animal entrails, particularly the liver. For anyone interested in early historical developments, the review by King and Meehan[2] is an excellent source.

The correlation of clinical and autopsy findings during the 18th century was a major contribution to the developing field of medicine. Subsequent extension of these gross observations with the addition of microscopy, bacteriology and chemical analyses expanded the scope of the post-mortem examination and kept the autopsy in the forefront of medical progress.

Despite rapid advances in medical science in this country, at the turn of the 20th century, much of medical education remained at a low level. The Flexner Report, in 1910, was highly critical of medical education in the United States. Strong support for pathology and the autopsy was recommended in this report. With this impetus, autopsy availability and percentage rates soon became important factors in accreditation of hospitals. American Board certification introduced rigid standards for pathology training and the average level of competence rose.

Three significant developments followed World War II. For a variety of reasons, including stricter standards of accreditation and enhanced public awareness, autopsy rates in hospitals rose sharply. The number of autopsies performed as part of "routine" hospital pathology services increased greatly.

During this same period, clinical laboratory "tests" became increasingly important in medical practice. As reimbursement for these procedures was assumed by third party insurance carriers, the clinical laboratories became one of the financial centers of the hospital. As the conduct and management of the clinical laboratories became more complex, the pathologist had less time for autopsy studies. Training in autopsy techniques also suffered. Coincidentally, government funds became available for research and specifically, experimental research. The latter demanded publications, which, in turn, brought about professional reputation, academic advancement, salary increases and more research grants. As a result, pathology in academic centers, as well as in community hospitals, was undergoing a metamorphosis.

While these forces were at work within pathology laboratories, in the mid 1950's, critical voices began to be raised by clinicians. The autopsy became the focus of attack. Issac Starr's JAMA editorial in 1956 noted that the era was "characterized by an increased reliance on experiment as a means of acquiring medical knowledge."[3] Starr also denied that any research of importance was coming from studies being made at routine autopsies. This attack by a prominent internist aroused spirited responses from pathologists.[4]

Over the past two decades, we have seen a reduction in the use of the autopsy for the teaching of medical students and residents and a significant decrease in the number of autopsies performed in many institutions.

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An earlier Professional Activity Study (PAS) showed that autopsy rates have been declining steadily since 1965 in U.S. hospitals.[5] In a cohort of 54 PAS hospitals, the mean autopsy rate declined from a high of 41.1% of all deaths in 1964 to 34.9% in 1972. For all U.S. hospitals, the rate fell from 29.0% in 1970 to 22.2% in 1973.

Lowe's[6] more recent PAS review indicates the downward trend is slowly continuing. The mean autopsy rate for all PAS hospitals in 1975 was 21.7%.

This nationwide trend has been mirrored in the experience of Connecticut hospitals. A comparison of numbers of autopsies performed and percentages of deaths autopsied for the years 1959, 1969 and 1979, at a university teaching hospital (Yale-New Haven) and a community hospital (Lawrence and Memorial) in this state, are seen in Table 1.

Table 1
NUMBER OF AUTOPSIES AND AUTOPSY RATES: 1959, 1969, 1979

	1959		*1969*		*1979*	
Hospital	*No.*	*%*	*No.*	*%*	*No.*	*%*
Yale-New Haven (900 beds)	847	65%	637	41%	396	30%
Lawrence and Memorial (313 beds)	171	60%	152	41%	121	33%

I have alluded to some attitudes and developments which have contributed to a de-emphasis of the autopsy. Another major factor has been the impression of some, that with today's sophisticated, invasive and non-invasive, diagnostic techniques, there is little to be learned from the autopsy. A more objective observation might be that these specialized procedures do not compete with the autopsy, nor do they diminish its importance. The autopsy is needed for their proper evaluation.

Abolishing the requirement for hospitals to perform a minimum percentage of autopsies, by the Joint Commission on the Accreditation of Hospitals (JCAH), has also had a negative impact. This decision, made in 1971, apparently was reached because the commission could not settle on a minimum rate higher than the 20 per cent applicable to all hospitals.

In recent years, there also appears to have been an inverse relationship between the increasing incidence of malpractice actions and further declining autopsy rates. In some instances, the desire for maintaining a low profile appears to have blunted the once aggressive pursuit of autopsy permissions and the willingness to review patient care, expose diagnostic and therapeutic errors, and learn from them.

In fact, documented instances, where the performance of an autopsy has been a major factor in a malpractice suit, are very rare. More often, the thorough post-mortem examination has supported the defense of a physician who has delivered adequate medical care.[7]

Having reviewed some historical aspects and trends, I would now like to consider benefits the autopsy offers to clinical medicine. These include a significant contribution to medical education and to the assessment of the overall quality of medical practice. The autopsy also offers methods for evaluating diagnostic techniques, therapeutic measures and new and developing surgical approaches. In addition, vital statistics become more reliable and the autopsy serves as a fruitful source for research.

Medical Education

The education of a physician begins when he enters medical school, continues through housestaff training and spans the years of his active practice. If "the goal of medical education is the transmission of knowledge of disease and the art of the use of such knowledge,"[8] the autopsy plays a major role in this process. "The autopsy room is not only the very first place a student can see and feel disease. There, he is exposed to the elation of a diagnostic coup, to the problems of uncertainty and the unknown that remains medical practice."[9]

During the ensuing years of training and practice, the goal of medical education does not change and the autopsy plays a major role in the self appraisal of the physician's skills.

In many instances, the autopsy also offers an opportunity to share an education experience with the larger medical community. This is achieved through departmental or staff reviews as well as clinicopathologic conferences (CPC). The latter, introduced as formal teaching exercises early in this century by Cabot at the Massachusetts General Hospital, continue to be an important feature of educational programs at the majority of teaching hospitals in the country. Transcripts of the Cabot Cases remain a central feature of the *New England Journal of Medicine,* and according to Relman, one of the most popular.[10]

Many lessons have been learned from the autopsy. Cooper[11] pointed out that the diagnosis of bacterial endocarditis was more often missed than made. The high incidence of pulmonary embolism, often clinically undetected, was brought to our attention by postmortem studies. Careful dissection by Lev and Lenègre[12 13] have given us a better understanding of the cardiac conduction system. Roberts'[14] coronary artery studies have shown us that thrombosis often follows, not precedes, myocardial infarction. Other recent entities, now better understood on the basis of postmortem studies, include such diverse conditions as idiopathic hypertrophic subaortic stenosis, asbestosis, mesothelioma, adult respiratory distress syndrome, disseminated intravascular coagulation and angioimmunoblastic lymphadenopathy.

Quality of Medical Practice

There is an overlap in the role the autopsy plays in education and the evaluation of the quality of medical practice. The autopsy is one of the clinician's most readily available and reliable teachers. He needs the autopsy to confirm, clarify and correct diagnosis, to guide him in the discovery of new diseases and the detection of new patterns of old diseases.

In every era, there are those who think we have learned almost everything there is to know. However, there is ample and recurring evidence in the literature that the autopsy will disclose a significant number of erroneous or missed diagnoses, or clarify puzzling aspects of many cases. Many reports suggest that the types of errors have not significantly altered over a period of years.

In 1912, Richard Cabot reviewed 3,000 autopsies at the Massachusetts General Hospital, to determine clinical errors. At the same institution twenty five years later, Edward Gall found the same percentage of errors. In 1960, Gall reviewed another 1,000 cases at the Cincinnati General Hospital and found the same sizable percentage of error (more than 40%).[15]

Gall's comments are pertinent: "Each era has its own new diseases which tend, at first to go unrecognized. The autopsy had, indeed, taught its lesson well and old mistakes were now minimized. But each generation has its unique panorama of problems requiring the familiarity of autopsy elucidation."

A comparison of the accuracy of the clinical diagnosis of cancer in two time frames, 1917-1922 and 1955-1965, published by Bauer and Robbins, indicates some slight improvement in clinical acumen.[16] Wells' review of the earlier period pointed out a 32.6% incidence of clinically unsuspected malignancy.[17] Fifty years later, Bauer and Robbins noted an error rate of 26.2% and documented an additional 13.9% with an incompletely diagnosed tumor including unknown or incorrect primary sites.

The majority of such studies have unfortunately been retrospective, making it difficult to judge the clinical implications.

Britton's prospective study of 383 autopsies on 400 consecutive deaths (96% autopsy rate) at the Karolinska Institute is more meaningful.[18] The causes of death established prior to autopsy were compared with those made by the same clinician, after autopsy findings were available. The main cause of death was confirmed as correct in 57% of the cases and was in error in 30% of cases. In an additional 13%, it was impossible to make the diagnosis antemortem.

A further refinement of this study included the clinician's determination of the degree of certainty of his clinical diagnoses into "fairly certain" and "probable." In the "fairly certain" group, the error rate was 25% and in the "probable" group, it was 45%. Britton concluded that, beyond all doubt, the autopsy still reveals a considerable number of errors in the clinical diagnoses of patients dying in hospitals. Although the disease panorama and modes of treatment and diagnosis change, the error rate does not decrease over the years.

These observations demand that acquisition of such knowledge via the autopsy be continuous.

In a similar but more recent prospective study from Norway[19] involving 809 autopsies during 1975, Hartveit noted a 19% error rate in premortem diagnoses considered "clinically certain" and a 35% error rate in "clinically uncertain" cases.

It is more than apparent, from these and many other studies, that the autopsy represents the ultimate in the quality assessment of medical practice.

When the autopsy reveals that a diagnosis is incomplete or inaccurate, it does not necessarily reflect on the diagnostic skills of the physician. Autopsies provide an indication of how much all of us must still learn. The challenges provided by postmortem findings point the way toward improving patient care.

Evaluation of Diagnostic Aids

Along with the general decline of interest in the autopsy, there has been a growing tendency to rely on other diagnostic techniques such as radiology, nuclear medicine and laboratory tests. The autopsy has served as an effective method in evaluating these procedures. The understanding of EKG changes developed, over the years, through autopsy correlations. The non-specificity of liver scans was similarly clarified. The evolution of brain scan patterns in the differential of neoplasia and ischemic lesions are another example of this role of the autopsy.

We see no let-up in the development and application of increasingly sophisticated, invasive and non-invasive tools in the field of medicine. It is worth remembering that with all procedures, we are not only dependent on technologic advances, but, as importantly, on the training, experience and expertise of the physician who is interpreting the data.

Most recent has been the addition of ultrasound and Computerized Axial Tomography (CAT scans) to the diagnostic armamentarium. It is not rare for such technology and/or its interpretation to fail us.

With regard to ultrasound, normal pericardium has been interpreted as constrictive pericarditis, endometrial cysts confused with papillary adenocarcinoma of the ovary and non-effusive angiosarcoma of the pericardium interpreted as effusive pericarditis. False negatives in CAT scans have been reported at 13.8% by Jacobs and others.[20]

Anatomic studies remain the standard for evaluation of the accuracy and value of the overall diagnostic and therapeutic effort in clinical medicine.

Monitor Effects of Therapeutic Agents

Virtually every drug currently employed therapeutically has undesirable, often serious and occasionally fatal side effects. These reactions are manifold and increasing. Often the cure is worse than the disease. The autopsy will continue to serve well in the definition of untoward effects to such diverse medications and substances as phenacetin, steroids and halothane.

Today there is widespread use of dyes, preservatives, insecticides, pesticides and many other chemical and industrial products of low or slow toxicity. The hazards to health from these substances can be ultimately determined in the human being only by the autopsy.

Evaluate Surgical Techniques

There are many examples of improved surgical techniques resulting from earlier technical failures, demonstrated at the autopsy table. The autopsy has contributed greatly to the continued improvement of prostheses in both cardiac and orthopedic surgery. In this role, the autopsy continues to lead directly and indirectly to improved patient care.

Vital Statistics

Mortality statistics are increasingly being used to direct resources into the prevention and treatment of disease. Recognition of environmental hazards and the early detection of communicable diseases are dependent on similar data. As fewer autopsies are being performed, the per cent of confirmed diagnoses continues to fall. The true incidence of disease cannot be derived from death certificates based on clinical impressions.

Farr observed,

> "The clinician makes a guess on the death certificate that leaves everyone happy. He is happy because the chart is signed out. The medical librarian is happy because she can now report something specific like thrombus of the lenticulostriate artery or ASHD. The collector of morbidity and mortality rates is happy because he can tabulate this guesswork and call it 'vital statistics'."[21]

Without the autopsy, vital statistics are unreliable and the incidence of diagnostic and therapeutic error is unknown. Misdirection of efforts, appropriations and public education may follow.

Research

The field of research, utilizing autopsy tissues, is truly as broad as medicine itself and if developed properly, becomes an indispensable part of on-going research in the areas of carcinogenesis, environmental disease, atherosclerosis and aging.[22] The only limit to the use and application of the autopsy in research is the imagination of the investigator.

The cellular pathology of human disease, introduced by Virchow, through developments in microscopy, immunology, biochemistry and physiology, now is allowing us to correlate structure and function at the sub-cellular level. Through combinations of electron microscopy and biochemistry, we may now distinguish many of the important organelle functions. The application of immunofluorescence coupled with metabolic inhibitors, allows study of the roles of microtubules and microfilaments in cell movements, secretory processes and phagocytosis. Cytochemical markers are of importance in the study of surface membrane changes and malignant transformation. As Gall reminds us, "The best subject for the investigation of man's ills is man himself."[15]

Other Benefits

A further advantage, which should not go unmentioned, is that of the autopsy serving as a source of organ harvesting, corneae, human insulin and growth hormone.

Brief mention should be made of the emotional support the autopsy provides for the family.[23] A full understanding of the death may provide comfort and allay guilt feelings. A feeling of charity and fulfillment may follow the knowledge that a cornea or a kidney will brighten or lengthen the life of a living patient. The clear definition of the cause of the death may affect the application of insurance benefits. In the case of contagious or genetic diseases, there may be an immediate benefit to the family.

It is beyond the scope of this discussion to review the impact of the autopsy on society in general and on the criminal justice system. Excellent reviews are available on these subjects.[24 25]

Conclusion

Having reviewed some of the historical aspects and benefits of the autopsy, it is difficult to appreciate the reasons for the declining use of this examination. Clearly, the benefits are a strong argument for renewed support and utilization. With knowledge of the many contributions the autopsy offers to clinical medicine, it is my hope more physicians will be encouraged to vigorously seek autopsy permissions.

In the general field of education, we are beginning to see a return to the basics. This, in part, is a reflection of our times. Hopefully, this trend portends a return to one of the basics of clinical medicine—the autopsy.

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Computers in Laboratory Medicine

A Report of Progress

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Introduction

During the past two decades there has been a progressive growth of the role of clinical laboratories in the practice of medicine. Concurrent with increasing understanding of the biochemical and pathophysiologic aspects of disease, analytical technology has progressed to provide a wide variety of laboratory procedures which may be employed in the diagnosis and management of illness. During this period utilization of laboratory services has increased continuously at a rate of 10-20% per year, and only now does it show signs of reaching a plateau of maximal utilization. Automated analytical technology introduced during this past decade has made such testing easily accessible and veritably irresistible.

While automation of analytical procedures had been accomplished effectively, it was soon appreciated that the flood of laboratory data and the logistics of specimen processing and result reporting were often overwhelming the unchanged conventional manual systems employed by the rest of the laboratory. Patient charts often became clogged with a mass of disorganized paper, and unexpected or unrequested information often obscured the abnormalities which the physician sought to identify.

Just prior to 1970, early attempts were made to bring some order to the problem of managing laboratory information by using computers. Dr. Rappaport of Youngstown, Ohio, was one of the first to join an automated analyzer to a computer to produce an organized cumulative laboratory report and to begin to develop the concept of a laboratory information system.[1-3] A number of vendors began to develop turnkey systems[4] which initially were designed to translate the electrical signals from analytical instruments, accept manual results and produce laboratory reports primarily for Chemistry and Hematology. Many individual laboratories working with local hospital Data Processing Departments had varying success in adapting the

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central hospital computer to solve these problems.[5]

Out of these efforts there has come a growing consensus[6-11] of what the nature of a successful laboratory computer might be and of the effective role it can fulfill in the operation of a hospital clinical laboratory. Most recently an increasing number of vendors,[12-14] including some of the major computer manufacturers, are marketing such systems, and at present approximately 300 or more hospitals throughout the country have installed such systems.[15]

Laboratory Computers in Connecticut Hospitals

In preparing this communication, a telephone survey was conducted, interviewing pathologists or other key laboratory staff members of the 27 Connecticut hospitals of 150 bed size or larger, in order to determine the extent to which computers are now employed in hospital laboratories, what level of satisfactory function has been achieved, and what plans are currently being made to add new computer systems or change existing ones. (Table 1)

Table 1

26 Hospitals Interviewed - 150 Bed or Larger	100%
9 Have lab computers	35%
2 Recent turnkey systems	8%
2 Presently developing in-house	8%
5 Older systems - 6-12 yrs.	19%
4 Plans to be replaced	15%
1 To continue development	4%
17 Hospitals do not have computers	65%
3 Have contract or proposal	12%
14 Have no specific plans now	54%
8 Actively planning 6-24 mon.	31%
6 No present need defined	23%
20 Hospitals Expect to Have Computer by 1982	77%

Nine (35%) of these hospital laboratories reported that a laboratory computer system was actively serving some part of the laboratory operation.

Two (8%) of these laboratories have installed modern turnkey systems within the past 2-3 years and report full satisfaction with their performance.

Two (8%) hospital laboratories are currently developing in house systems with the cooperation of the hospital Data Processing Departments. Relatively limited applications are now operating on these systems.

Five (19%) hospitals have had functional laboratory computers for the significant period of 6-12 years. These include older turnkey systems and also some which were developed in-house. All of these laboratories express the conviction that their systems have been successful in solving many of their department's problems, but all recognize present inadequacies in meeting current needs. One of these, a large institution with a system developed in-house, is successfully pursuing continued development. The other four are now all seeking replacement with modern systems, and one of these has already submitted a proposal for certificate of need to the Commission on Hospitals and Health Care.

Seventeen (65%) hospitals do not now have an operating laboratory computer system, however, three (12%) of these hospitals have advanced plans; one with a contract being implemented and two ready for application to the Commission on Hospitals and Health Care.

Of the fourteen (54%) other hospital laboratories which do not now have specific plans for computer systems, eight (31%) are actively studying this question. They express recognition of a serious need and generally have set goals for planning and implementation of such a system within the next six to twenty-four month period. Only six (23%) of these laboratories have not yet considered a laboratory computer as an important part of their current plans.

On the basis of this data, it is noteworthy that there is already a relatively high level of laboratory computer utilization in Connecticut, and this utilization is currently rapidly expanding. With completion of current plans and expectations, it could well be that by 1982 or 1983 twenty hospitals (77%) in Connecticut will be using modern laboratory computer systems as part of their routine operation.

The Clinical Laboratory Computer - 1980

At its current state of development the laboratory computer system should be regarded as another complex laboratory instrument designed to facilitate all aspects of the operation of the laboratory.[11] The basic goal and purpose of this operation is to translate the physician's request for a laboratory test with accuracy, reliability and efficiency into a test result which has been presented to him in a legible and logical format at a proper time and place that he may use this information to best advantage in the care of his patient.[6] To that end it is important that as much of the process as is cost-effectively possible be accomplished within the computerized system.

The present generation of laboratory computer systems benefit from a fourth generation computer technology which shifts the emphasis from large central computers to the use of relatively small and less expensive mini-computers having phenomenal capacity for rapid data processing and storage. Although all systems should anticipate the need to communicate effectively and to function as part of a future hospital information system, in most circumstances the laboratory is now the initial clinical application of computers and is most likely to function independently within the laboratory.

The hardware of the computer includes a central processing unit (CPU) which manipulates the information and acts as a communications switchboard. A variety of electronic storage devices are attached to store information. Functional communication with the computer is accomplished through the use of a variety of devices. The most common one is the cathode-ray tube (CRT) which provides a screen to display messages and a keyboard by which inquiry or response can be accomplished. Additionally, printers provide a wide range of more permanent records for a variety of uses.

Special techniques such as mark-sense cards or special purpose keyboards may also be employed.

Residing within the computer are the programs or "software" which is the very elaborate set of instructions incorporating all of the detail of what the computer is intended to do.

While some hospital information systems already exist[16] which place terminals on each nursing station, most present laboratory systems begin with an order entry system in the laboratory. The nursing staff transfers the physician's requests to laboratory requisitions. These requests are entered into the system by a laboratory data clerk, thus preparing the computer to handle those tests. Patient identification information has already been acquired from the Admitting Department, probably by direct wire connection to the hospital's central computer which is used to process admission, discharge and transfer information.

At the appropriate time, the computer is instructed to prepare a collection list for each phlebotomist providing identification of patient, location, test request and specimen number together with labels required for each sample tube. Verification of completed collection is accomplished by a separate simplified accessioning program.

For each analytical station, work lists are then prepared so that there is a continuous control of the activity appropriate to the requests which have been made. Larger automated equipment is connected directly to the computer so that results are transferred without transcription. Manual results, first recorded on work lists, are then entered at terminals by the technologists who perform the tests. As groups of analytical data, either manual or automated, are transferred to the computer, special programs require that the technologist review the information, and often special flags are provided to identify abnormal or inappropriate results which may need special attention. Immediately upon acceptance by the technologist, data is transferred to the computer where it becomes available for inquiry or reporting without further delay of transcription. At the same time, the computer has been assisting and assuring the proper completion of the quality control functions required to maintain accurate and dependable analytical results.

The reporting of completed test results may be accomplished in a variety of ways to meet the particular needs of the clinical situation. As a first priority, all tests which have been flagged as stat may be reported immediately on terminals assigned to critical care areas such as the Emergency Room or ICU. For other areas which may lack such terminals, the technologist will be prompted by the computer to telephone immediately any stat or critical-value results, and an appropriate paper report may be prepared simultaneously in the laboratory for prompt delivery by messenger. More routine results will usually be delivered to the nursing units at selected intervals during the day (perhaps 9 a.m., noon, 2 p.m., 5 p.m.) in the form of nursing unit reports which show all of the daily work for each patient on that unit either as in-process or with the completed result. Each subsequent report inclusively replaces the previous report. Once each day, usually in the evening, a cumulative report recapitulates the entire laboratory data for the patient record in a logical sequential format, showing normal reference values and flagging abnormal results or those which differ significantly from previous analyses (Delta Check). It may also be possible to provide each physician with a summary report of all of the daily results of each of his own patients at a time convenient to his scheduled daily rounds.[6]

Meanwhile, within the laboratory, the information clerk has access to a terminal through which she may determine the status of any patient-specimen and the result when completed so that she is able promptly and accurately to respond to telephone requests for information from physicians who do not have printed reports immediately at hand. As a result of these features the physician can be assured of a prompt and dependable response to his request for laboratory data. Twelve to twenty-four hours of information-lag may be eliminated in many cases and the rate of error due to mistranscription and loss of information will be substantially reduced.

Another significant aspect of such a laboratory computer system is its contribution to the effective management of the laboratory itself.[10] Immediately, of course, the billing function can be accomplished by directly linking the activity files of the laboratory computer to the billing system of the hospital's computer. Often the avoidance of lost charges and the labor saving in this clerical function goes far to offset the cost of the computer system.[15] But beyond that, a variety of management reports of laboratory activity contributes not only to the quality control of the analytical procedures, but also to the process of assignment of personnel, planning and budgeting to meet changing laboratory conditions, and in general helping to assure that most effective utilization of laboratory resources is being achieved.

Future Developments of Laboratory Computers

Initial use of computers for laboratory purposes was generally confined to mathematical calculations and in such a role permitted employment of statistical analysis of laboratory data from large numbers of patients to establish normal reference ranges and to determine the accuracy and precision of laboratory procedures. This information is critically important in the interpretation of laboratory results. This methodology continues to play a regular role in carrying out the internal and interlaboratory quality control and performance evaluation programs which are an essential part of laboratory operation.

As modern computer laboratory information systems are introduced, it is apparent that one of its most useful contributions has been the ability to prepare and provide a daily updating of a cumulative report of all laboratory results arranged in a logical format to facilitate monitoring of the progress of the patient's status over a period of time. Additionally, simple mathematical routines enable the flagging of abnormal or significantly changing results as well as the calculation of some useful derivative values such as AG ratio, ion-gap, etc. At the same time, accurate reference ranges specific for the age and sex of the individual patient can be provided as part of the report. This enhanced sequential reporting of laboratory data has brought order and interpretability to this segment of the medical record.

Many investigators[17-22] are currently developing new applications of computer systems utilizing the mathematical techniques of discriminant analysis and Bayes theorem to provide an interpretive synthesis of the significance of multiple test results and to define the most effective testing strategy to be pursued in investigating initial abnormal test results or diagnostic problems. These data reduction schemes will probably increase the specificity and predictive value of available laboratory data and permit more cost effective utilization of laboratory services. Ultimately these will become a standard component of the computerized laboratory report.

While most hospitals already have a central business computer or computer service, the introduction of a computer system into the clinical laboratory is generally the first major application of the computer to clinical functions. As further development of hospital information systems occurs, the laboratory system will be able to join with similar systems in such areas as Radiology and Pharmacy as well as nursing units to form a hospital-wide communications network, making all the essential data readily available to the physician as required. What innovative enhancements of information are to be achieved by this level of clinical data processing remain to be seen during this next decade. By that time clinical laboratories will have provided the physicians of Connecticut with an ample introduction to the power and limitations of computer systems in medical care so that they will be fully prepared to make use of those new opportunities.

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Toxic Megacolon with Campylobacter Colitis

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M. H. SANGREE, M.D.

ABSTRACT—*Campylobacter fetus* subspecies *jejuni* appears to be a common enteric pathogen. In most cases a self-limited diarrheal illness is noted. In this report, a patient with severe colitis is described. Crypt abscesses were present microscopically and 'toxic megacolon' developed suggesting a diagnosis of ulcerative colitis. Stool cultures and responses to appropriate treatment, however, revealed that *Campylobacter fetus* ss. *jejuni* was the cause of this patient's illness. This organism should be considered in the differential diagnosis of acute ulcerative colitis.

Introduction

Recently, *Campylobacter fetus* subspecies *jejuni* has come to be recognized as a common human enteric pathogen.[1] As the name implies, the principal site of infection has appeared to be the small intestine. In most cases, the illness is self-limited.[2] We have recently encountered a patient with a severe form of this disease. Our patient had an acute colitis with this infection and developed 'toxic megacolon'. Colonic involvement simulating nonspecific idiopathic ulcerative colitis has been previously noted with this organism.[3] This report illustrates that severe disease, in which corticosteroid and surgical treatment would otherwise be considered, can occur with *Campylobacter* infection.

Case Report

The patient, an 83-year-old Caucasian female, was admitted to Waterbury Hospital Health Center with watery diarrhea and fever in October 1979. The patient was well until 3 days prior to admission when vomiting and diarrhea developed. Fluids, Kaolin and pectin mixture, and lopermide hydrochloride did not control the diarrhea which was the most prominent symptom. Fever and dehydration led to her admission.

The past history included an appendectomy, cholecystectomy, hysterectomy and local excision of a breast cancer. Mild hypertension had been controlled with hydrochlorthiazide.

Physical examination revealed a temperature of 101°F, a pulse of 110, and a blood pressure of 160/70. The patient was confused and acutely ill. Her abdomen was mildly distended and bowel sounds were normal. Lower abdominal tenderness was present. Rectal exam revealed liquid brown stool which was strongly positive for occult blood.

Routine laboratory data was normal except for a white blood cell count of 6300 with a differential of 50 segs, 30 bands, 15 lymphs, and 5 monos on admission. The initial radiograph of her abdomen revealed a non-specific gas pattern. A fecal specimen was microscopically positive for leukocytes and red cells.

She was treated with intravenous fluids; diarrhea continued. On the third hospital day her temperature rose to 102°F, abdominal distention dramatically increased, and rebound tenderness developed in the right lower quadrant. A repeat white blood cell differential revealed 67 bands. A repeat film of the abdomen showed dilated small and large bowel. At sigmoidoscopy, friability was noted. Rectal biopsy confirmed an acute colitis with crypt abscess formation. Stool cultures done on admission were reported on day three as demonstrating *Campylobacter fetus* subspecies *jejuni*. The patient was treated with erythromycin and improved although the abdominal distention actually worsened prior to complete recovery (Figure 1). Contrast studies done without cathartic preparation revealed a right-sided colitis (Figure 2). Gross blood appeared briefly on the 9th day in hospital although sigmoidoscopic exam was then normal.

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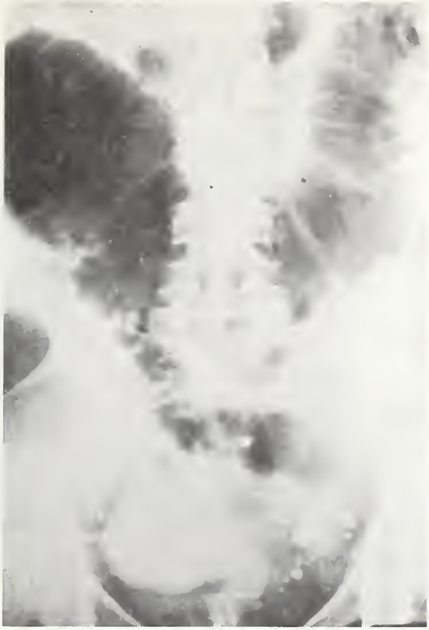

Figure 1
Abdominal film demonstrating colonic dilatation on day 4. The transverse colon was most dilated at this time, measuring 11 centimeters.

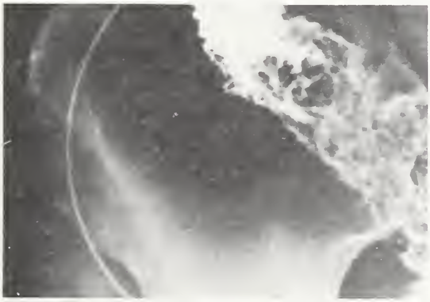

Figure 2
Barium study revealing ulceration in the right colon.

Concomitantly, the patient's daughter developed self-limited, mild diarrhea. The daughter, who lived in the same house as the patient, recalled that their pet dog was the first in the household to develop diarrhea. Stool cultures confirmed the presence of *Campylobacter* in both daughter and dog.

Followup after her 15 day hospitalization revealed no recurrence and a normal barium enema at three months.

Discussion

Campylobacter is now recognized as a very common cause of infectious diarrhea in many parts of the world. In many centers it is isolated in stool cultures more commonly than *Salmonella* and *Shigella.*[4] This has also been the case at our institution. A commercially available media and technique involving microaerophilic culture at 42°C has been used in all stool cultures for enteric pathogens since June 1979. In the first 6 months of use, *Campylobacter* was cultured in 7.9% of 468 specimens. *Salmonella* or *Shigella* species were demonstrated in 2.7% of specimens and 89.4% were negative for enteric pathogens. The mechanism by which this organism causes diarrhea is not fully understood. Autopsy studies have incriminated a small bowel process; however, Lambert et al[3] have recently documented that the colon is frequently involved. As in at least one of their cases, our patient also had crypt abscess formation on rectal biopsy. In addition, our patient developed signs of systemic toxicity and gross dilatation of the colon. The term "toxic megacolon" has been used to describe such patients. Although 'toxic megacolon' originally appeared to be a complication of idiopathic ulcerative colitis, it is now clear that the syndrome may complicate other colitides, and recently *Salmonella* organisms have been shown to cause an acute colitis with dilation.[5]

The case reported demonstrates once again that an acute colitis may be seen with *Campylobacter.* 'Toxic megacolon' is probably a manifestation of severe colitis although other factors have been implicated in its pathogenesis. Antidiarrheal drugs, barium studies, and electrolyte abnormalities have been temporally associated with the appearance of dilation in colitis. Its appearance in ulcerative colitis is used as evidence that surgery should be urgently considered since the mortality with continued medical treatment is so substantial. The necessity of thorough microbiologic evaluation in patients with acute colitis is illustrated by this report. The treatment of idiopathic inflammatory bowel disease is different from the treatment of a specific infectious colitis. The former often entails the use of steroids and surgery. If a specific infectious etiology is discovered for which efficacious treatment exists, however, these measures can be avoided.

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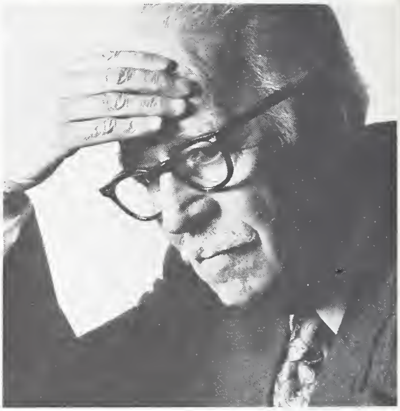

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Gynecologic Oncology: Cancer Update

(First of Two Parts)

PETER E. SCHWARTZ, M.D. AND DANIEL KAPP, M.D.

ABSTRACT—The recent changes in the occurrence, diagnosis, staging, and treatment of gynecologic malignancies have been reviewed. The close interaction and cooperation between physicians in the community and radiation therapists and gynecologic oncologists specially trained and familiar with the management of this group of malignancies are imperative to insure optimal results and minimal morbidity. The need not only for technically skillful, but also for emotionally supportive and compassionate therapy is of particular importance in the care for patients with gynecologic malignancies.

Introduction

During the past decade significant changes have occurred in the frequency of the common cancers of the female reproductive organs in the United States. Cervical cancer, the most common cancer of the female reproductive organs until approximately 1970, is now the third most common cancer in the female reproductive organs.[1] Endometrial cancer is the most commonly reported cancer in the reproductive organs, and ovarian cancer is second. An increased frequency of a rare cancer of the vagina, the clear cell adenocarcinoma, has been noted during the past decade, most often in association with in-utero exposure to diethylstilbestrol.[2] Significant advances have been made in the chemotherapy and radiation therapy of ovarian cancers, and the introduction of the radioimmunoassay for chorionic gonadotropin has resulted in an exquisitely sensitive means of monitoring therapy for gestational trophoblastic disease.[3-5] The purpose of this paper is to present an update in gynecologic oncology for practitioners. To accomplish this, this paper will discuss gynecologic malignancies by sites and will review diagnostic techniques, clinical staging and management of these malignancies.

Cervix

The traditional high-risk factors for precancerous changes as well as invasive cancer of the cervix include early age of first intercourse, multiple partners, child bearing before age 17, cigarette smoking, and lower socioeconomic backgrounds.[6 7] Recently an increased incidence of precancerous changes and invasive cervical cancer has been associated with the presence of basic protein in sperm.[8] Indeed, a "high risk" male for cervical cancer in his contacts has now been identified.

Advances in the detection and office management of preinvasive changes of the cervix have been attributed to the wide-scale utilization of the Papanicolaou (PAP) smear and subsequently the use of colposcopy to establish the site that abnormal PAP smears cells may have arisen from.[9] Interest in the role of cryocauterization and more recently laser beam therapy has resulted in many series which have demonstrated a large decrease in the incidence of cone biopsies for the diagnosis and treatment of the abnormal PAP smear.[10]

However, questions have been raised regarding indications for PAP smears and the role of local treatment in the management of abnormal PAP smears. Reports from Canada and the United States would suggest that routine use of the annual PAP smear in those patients who are not at a high-risk for preinvasive and invasive cancers of the cervix is probably unnecessary once the patient has been established to have negative PAP smears for three consecutive years.[11 12] These studies have indicated that the frequency of cervical intraepithelial neoplasia is so low in this particular group of patients that one might then obtain PAP smears on an every three-year interval and subsequently at five-year intervals. This has caused consternation among clinicians mainly because it remains virtually impossible to define who is a high-risk patient for an abnormal smear. Indeed changing sexual mores, undefined "early age of first intercourse," "multiple partners," and increased cigarette smoking among females, results in a significant number of patients who would fall into the so-called "high-risk group." What is clear from the Canadian and American studies is that the training of cytotechnologists and pathologists in reading cytologic smears should be reviewed.

Experience at Yale-New Haven Hospital (YNHH) would indicate that the annual PAP smear is the most important test for detecting preinvasive and early invasive cancers of the cervix.[13] One should not use the

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PAP smear as the sole screening technique when the cervix is grossly abnormal and the PAP smear comes back with benign changes. Clinical suspicion must be maintained at all times and biopsies must be liberally employed when the clinician is suspicious of an abnormality of the cervix which is unexplained by a PAP smear.

The role of cyrocauterization of the cervix has undergone close scrutiny because of reports of invasive squamous cell and adenocarcinomas of the endocervix developing in patients treated by cryocauterization for cervical intraepithelial neoplasia (CIN).[14] These reports indicate that cryocauterization may be employed in managing the precancerous changes of the cervix, but also point out that the patient must be reliable and return for routine follow-up, as local therapy to the cervix may only be of a temporary nature. Contraindications to cryocauterization of the cervix include the failure to obtain an endocervical curetting and the failure to visualize the entire transformation zone by colposcopy. It is the policy at YNHH that patients who fall into the latter two groups should undergo a cold knife cauterization of the cervix to assess the endocervical canal and the extent of the lesion present.

Squamous cell cancer represents approximately 90% of cervical cancers and is most successfully managed in the early stages of disease.[15] The management of advanced stages of squamous cell cancers has not resulted in dramatic improvement of overall survival in recent years.[16 17] The current F.I.G.O. staging system for invasive cancer of the cervix is present in Table I.

Table I

F.I.G.O. STAGING SYSTEM FOR CARCINOMA OF THE CERVIX

Invasive Carcinoma	
Stage I	Carcinoma strictly confined to the cervix (extension to the corpus should be disregarded).
Stage Ia	Microinvasive carcinoma (early stromal invasion).
Stage Ib	All other cases of Stage I. Occult cancer should be marked "occ".
Stage II	The carcinoma extends beyond the cervix but has not extended onto the pelvic wall. The carcinoma involves the vagina, but not the lower third.
Stage IIa	No obvious parametrial involvement.
Stage IIb	Obvious parametrial involvement.
Stage III	The carcinoma has extended onto the pelvic wall. On rectal examination there is no cancer-free space between the tumor and the pelvic wall. The tumor involves the lower third of the vagina. All cases with a hydro-nephrosis or non-functioning kidney.
Stage IIIa	No extension onto the pelvic wall.
Stage IIIb	Extension onto the pelvic wall and/or hydronephrosis or non-functioning kidney.
Stage IV	The carcinoma has extended beyond the true pelvis or has clinically involved the mucosa of the bladder or rectum. Bullous edema as such does not permit allotment of a case to Stage IV.
Stage IVa	Spread of the growth to adjacent organs.
Stage IVb	Spread to distant organs.

The introduction of megavoltage radiation therapy machines has resulted in the ability to deliver higher doses without excessive skin or other normal tissue reactions with some increased local and regional control of cancer.[18 19] Unfortunately, many patients still die of regional failure and distant spread, with regional failures being most frequent in patients with advanced stage lesions.[20] In an attempt to obtain better overall survival, extended field radiation therapy to cover paraaortic lymph nodes was introduced.[21] Staging laparotomies have been recommended prior to the initiation of extended field irradiation in order to identify which patients are at high risk for having lymphatic involvement, to attempt to debulk large involved lymph nodes in the pelvic and paraaortic areas in order to make radiation therapy more effective, and to eliminate unnecessary irradiation to the bowel and stomach resulting in injuries when extended field irradiation is employed.[22] However, the added mortality of the surgical procedure in relation to its possible benefit has been questioned and such staging procedures should be considered investigational.[23]

Pretreatment lymphadenectomy studies have revealed that as the patient's clinical stage advances, or as the primary tumor becomes more bulky, the frequency of local and regional lymph node involvement increases.[24] Patients with bulky Stage IIb, III, and IV cancer of the cervix appear to have a 30 to 50% incidence of paraaortic lymph node spread. Pretreatment selective lymphadenectomy studies have clearly identified patients at high risk for paraaortic lymph node involvement from cervical cancer, but have yet to demonstrate long-term survival in those patients who have large grossly involved lymph nodes. Long-term survival when paraaortic nodes are involved appears to be limited to that group of patients who have microscopic disease identified in the lymphadenectomy specimen. Routine paraaortic nodal irradiation with moderate doses (4500 - 5000 rads) should be considered in high-risk patients who are in otherwise good health, without subjecting these patients to the additional hazards of a staging laparotomy. Preliminary results of this approach, in a non-randomized trial, have suggested an improvement in survival without excessive complications in Stage IIb patients treated with extended fields.[25]

An experimental program is now underway employing intraoperative paraaortic irradiation at the time of pretreatment selective lymphadenectomy in order to give intense radiation to the paraaortic lymph node area at a time when the bowel can be displaced from the radiation field.[26] No long-term results from this study are yet available.

Large, bulky tumors may possibly be associated with an increased number of microscopic areas of necrosis with presumably increased numbers of anoxic and hypoxic tumor cells. These viable hypoxic cells are relatively radio-resistant and may be responsible for local treatment failures. One attempt to overcome this radio-resistance has been to administer radiation therapy while the patient is in a hyperbaric oxygen chamber.[27 28] Variable results have been reported using this technique with conventional fractionation or irradiation, but some decrease in local recurrence rates and improved survival has been noted in one recent series, especially in patients irradiated with higher doses per fraction.[29] Other approaches have included the use of hypoxic cell sensitizers, agents which when administered orally can reach the hypoxic cell, mimic oxygen and cause increased killing of hypoxic cells exposed to radiation.[30] Alternatively, some centers have investigated the role of external beam irradiation with fast neutrons and the intracavitary placement of the neutron emitter Californium 252 in an attempt to destroy these hypoxic cells.[31 32]

There is a renewed interest in radioactive needle implants to boost the radiation dosage in the presence of large, bulky cervical cancers and remote controlled intracavitary placements (e.g., Cathetron, Ralstron) have also been employed to provide intense local radiation.[33-35b] A small series of patients have been treated with irradiation and hyperthermia induced by microwaves with dramatic preliminary results.[36 37] Adjuvant chemotherapy including the use of hydroxyurea has been reported to increase the initial response rate of patients with advanced-stage cervical cancer.[38]

Histo-pathologic correlations have been obtained which suggest that as the grade of the cancer increases the risk of dissemination increases and that the presence of tumor invading blood vessels as noted in the biopsy specimen is a poor prognostic sign.[39] Diagnostic radiologic techniques employing computerized axial tomography and ultrasound have been advocated for localizing external beam irradiation fields as well as for directing biopsies of suspected metastases.[40-43]

At YNHH invasive cancers of the cervix are treated as follows:[15] Micro-invasive squamous cell carcinoma of the cervix (Stage Ia) is treated with a simple hysterectomy. Young patients with early invasive well differentiated squamous cell cancer of the cervix, that is Stage Ib, with cancer less than 2 centimeters in maximum diameter undergo radical hysterectomy and bilateral deep pelvic lymphadenectomy provided there is no evidence of spread to the common iliac or paraaortic lymph node chains. The advantages of surgery are complete removal of the primary cancer, retention of ovarian function and the avoidance of possible strictures in the vagina associated with radiation therapy.[44] Patients treated in this fashion are a highly selected group of individuals. Patients who are not suitable for radical surgery, e.g., older patients, poorly differentiated cancers, patients with medical contraindications to surgery, and patients with tumor greater than 2 centimeters in diameter are usually treated with intracavitary and external beam radiation therapy. Patients with Stage II, III, and IV squamous cell cancers are routinely treated with intracavitary and external beam radiation therapy. The external beam therapy is generally extended to include the paraaortic areas in those individuals with poorly differentiated carcinomas and advanced stage cancers. Routine hysterectomy following completion of radiation therapy is occasionally offered to those patients who have unusual variants of squamous cell cancer of the cervix including barrel-shaped cervices and extension of the cancer to involve the endometrium and myometrium.[45-47] It remains controversial, however, whether increased patient survival is obtained by this. When simple hysterectomies are considered in management of squamous cell cancers of the cervix, one must reduce the intracavitary radiation therapy component in order to avoid excessive injuries to the bladder or rectum, secondary to the combined approach.[48]

Adenocarcinoma is the second most common cancer of the cervix and is treated quite similarly to squamous cell cancer. Radical hysterectomies are often employed for management of early Stage Ib cancer, whereas intracavitary and external beam radiation is chosen for advanced Stage Ib and Stage II, III and IV cancer. Experience at YNHH suggests that patients with Stage II adenocarcinomas of the cervix have a somewhat higher tendency to fail following radiation treatment than do patients with squamous cell carcinoma.[15] For the past decade a simple hysterectomy has been recommended following completion of the radiation therapy program for adenocarcinoma of the cervix.[49] Here too, however, the value of the adjunctive hysterectomy for adenocarcinomas of the cervix has been questioned.[50]

Successful management of recurrent cervical cancer requires aggressive surgery in the form of exenterations when the tumor is bulky, and less frequently radical hysterectomies and pelvic lymphadenectomies when the patient has a focal central recurrence. Chemotherapy trials employing single agent and combination chemotherapy have been very disappointing. It would appear from a small number of series that the agent that is most consistently active in controlling recurrent squamous cell cancer of the cervix is cis-diamminedichloroplatinum.[51]

Endometrium

Endometrial cancer is now the most common malignancy of the female reproductive organs in the United States.[1] The International Federation of Gynecologists and Obstetricians (F.I.G.O.) staging system for endometrial cancer is presented in Table II. Attention has been focused on the role of exogenous hormones in association with the recent increase in endometrial cancer. Retrospective studies of women with endometrial cancer have generally demonstrated that exogenous hormones do increase the relative risk of developing endometrial cancer to varying degrees and these studies suggest that the dosage of medication and the time of exposure to exogenous hormones may be of significance.[52]

Table II

F.I.G.O. STAGING SYSTEM FOR ENDOMETRIAL CANCER

Stage 0	Carcinoma-in-situ. Histological finding suspicious of malignancy. Cases of Stage 0 should not be included in any therapeutic statistics.
Stage I	The carcinoma is confined to the corpus.
Stage Ia	The length of the uterine cavity is 8 cm or less.
Stage Ib	The length of the uterine cavity is more than 8 cm.
	The Stage I cases should be subgrouped with regard to the histologic type of the adenocarcinoma as follows: GI—Highly differentiated adenomatous carcinomas. G2—Differentiated adenomatous carcinomas with partly solid areas. G3—Predominantly solid or entirely undifferentiated carcinomas.
Stage II	The carcinoma has involved the corpus and the cervix.
Stage III	The carcinoma has extended outside the uterus but not outside the true pelvis.
Stage IV	The carcinoma has extended outside the true pelvis or has obviously involved the mucosa of the bladder or rectum. A bullous edema as such does not permit allotment of a case to Stage IV.

The presence of malignant squamous elements has been reported as a significant prognostic factor in patients with endometrial cancer.[53,54] Initial reports suggested that the adenosquamous carcinomas, i.e., the presence of squamous cell cancer in association with adenocarcinoma result in a terrible prognosis, but more recent data would suggest that the grade of the adenocarcinoma present is the most significant prognostic factor for patients with adenosquamous carcinomas of the endometrium.[55] An association between the development of adenosquamous cancers and exogenous hormones has not been identified.[56] Indeed, most patients developing endometrial cancer in association with exogenous hormone therapy tend to have histologically well differentiated lesions.[56]

The role of preoperative radiation in the management of early stage endometrial cancer remains unclear. Preoperative radiation, either intracavitary or external beam, can destroy all microscopic evidence of residual intrauterine cancer in 50 - 72% of cases where hysterectomy was performed 4 - 8 weeks after irradiation.[57,58] Several reports have suggested that prognosis is dependent upon the presence of residual cancer in the postirradiation hysterectomy specimen, but other studies have failed to confirm this.[59-62] The decrease in viable tumor as a function of time prior to hysterectomy and the difficulty in establishing histopathologically the viability of residual cancer cells may aid in explaining the varying results. Intensification of the intracavitary dose regimen appears to have improved local control in one large series.[63] However, other studies would suggest that intracavitary radium has little influence in the overall survival of patients with early stage endometrial cancer.[64]

The established role of radiation therapy in early stage cancer of the endometrium is to reduce the incidence of vaginal vault recurrences following hysterectomy.[65] It remains unclear as to whether the radium is more appropriately applied preoperatively or postoperatively with a composite review of the literature demonstrating a similar reduction in vaginal vault recurrences.[64]

Several studies have established depth of uterine invasion and tumor grade to be of prognostic importance in Stage I endometrial carcinoma, with histologic grade felt to be of predominent importance.[66-68] As the degree of differentiation worsens, the chance of deep myometrial invasion and metastases to deep pelvic and paraaortic lymph nodes increases.[69] Patients with biopsy-proven lymph node metastases have a poor prognosis.[65] Since depth of myometrial invasion and pelvic lymph node involvement can not be accurately identified preoperatively, the employment of preoperative intrauterine and vaginal radium followed in one to five days by a total abdominal hysterectomy and bilateral salpingo-oophorectomy has been advocated to permit accurate staging.[70] Preliminary results have been excellent.[71] The role of extended field irradiation in the treatment of patients with advanced stage endometrial cancer or patients with positive pelvic or paraaortic lymph nodes is uncertain at this time, but warrants investigation in high-risk patients.

The presence of steroid receptor proteins has been well established in breast cancer, and more recent work would suggest that similar receptors are present in the uterus.[72] While the presence of steroid receptors is well established in breast cancer as a prognostic factor, results to date are more equivocal in endometrial cancer. Attempts to correlate the grade of endometrial cancer with the presence or absence of estrogen and progesterone receptor protein have yielded divergent results.[73,74] It is clear that advanced and recurrent endometrial cancer, particularly histologically well differentiated cancer, will respond to progestational therapy, whereas poorly differentiated cancers do not usually respond to such therapy. However, a recent study showed no relationship between objective response and histologic recurrence of metastases.[75,76] Studies are not yet available to demonstrate that receptor protein levels will influence the selection of a progestational agent for the management of advanced and recurrent endometrial cancer.

A preliminary report suggests that there may be a role for anti-estrogen therapy particularly in grade I and grade II recurrent endometrial cancer and clinical trials are now in progress to define response of such tumors to anti-estrogen therapy.[77] An important aspect of studies at YNHH is to see whether the response to anti-estrogen therapy correlates with the presence or absence of estrogen receptor protein.

The present management for Stage Ia, Grade I, endometrial cancer at YNHH is to perform a total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH - BSO) and apply radium to the apex of the vagina approximately seven days postoperatively. If the patient is found histologically to have deep myometrial invasion, external beam radiation therapy to the pelvis is instituted two to three weeks postoperatively. Patients with Stage Ib Grade I cancer, all patients with Grade II lesions and Stage Ia Grade III lesions receive an intracavitary radium or cesium application followed by TAH - BSO 48 to 72 hours later. Patients with Stage Ib, Grade III lesions receive whole pelvis and intracavitary radiation prior to TAH-BSO. Patients with Grade III cancers are at a particularly high-risk for pelvic and paraaortic lymph node metastases and these sites are sampled at the time of the hysterectomy. Peritoneal washings are routinely obtained for cytology studies upon entry into the peritoneal cavity. Patients with deep myometrial invasion in the hysterectomy specimen or evidence of pelvic or paraaortic lymph node spread are then treated with external beam radiation, the size of the field dependent upon whether pelvic or paraaortic lymph nodes are involved.

Patients with Stage II cancer receive intracavitary and external beam irradiation prior to TAH - BSO. Patients with Grade III lesions are treated with extended field irradiation to cover the paraaortic areas prior to surgery. Stage III is defined as cancer involving adjacent pelvic structures. Patients with cancer infiltrating the parametria are treated with intracavitary and external beam radiation therapy followed by TAH-BSO when possible. Patients found to have a pelvic mass which may represent a metastasis to an ovary or a separate concurrent ovarian cancer, undergo an exploratory laparotomy, resection of the pelvic mass, TAH - BSO, peritoneal cytologic washings, and sampling of pelvic and paraaortic lymph nodes. Postoperative radiation therapy is based upon the histologic assessment of the surgical specimens. When concurrent ovarian cancer is confirmed these patients usually receive whole abdominal irradiation with additional radiation to the pelvis. Patients who have paraaortic lymph node involvement may receive a boost of radiation therapy to the paraaortic area. Clinical Stage IV disease is confirmed histologically and palliative radiation is recommended to the uterus to control bleeding. Patients are then placed on progestational therapy.

Cytotoxic chemotherapy has been assessed in advanced and recurrent endometrial cancer. Single agent therapy has generally been unsatisfactory. Combination chemotherapy employing 5-fluorouracil, adriamycin, cyclophosphamide, and progestins or cis-platinum and adriamycin in combination with progestins, have been reported to have a significant response rate although the survival rate remains unimpressive.[78, 79]

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The AMA and Health Insurance

- Nine out of 10 Americans have private or "public" health coverage.
- Some three out of four under 65 have some form of private catastrophic coverage.
- In 1978, private insurers paid out $45.4 billion in benefits, or 27 per cent of all personal health-care costs.
- Medicare in December 1978 was available to 27 million people; Medicaid, to 22.4 million.

There is a belief that legislation focused on private, employer-paid catastrophic coverage, with special provision for low-income employers and consumers, as in Long and Dole catastrophic bills, is about all that can be budgeted at this time—ruling out highly federalized bills.

The AMA believes in adequate health coverage for all Americans. It sponsored NHI legislation every year from 1970 to 1978. In 1979 the House of Delegates adopted four principles:

- Minimum standards of adequate benefits for health insurance policies, with deductibles and coinsurance to contain costs.
- A system of uniform federal, state, and local government benefits for those who cannot provide for their own medical care.
- A nationwide private-insurance program to make catastrophic coverage available, with government reinsurance if necessary.
- Administration at the state level, with national standardization through federal guidelines.

As for NHI legislation focused on greater economic competition in health insurance through multiple options, the AMA has testified that quality safeguards must not be sacrificed to cost considerations.

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Intraocular Lens Implantation

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Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A consensus development conference on intraocular lens implantation was held at the National Institutes of Health on September 10-11, 1979.

The NIH consensus development program brings together practicing physicians, biomedical research scientists, consumers, and others in an effort to reach general agreement on the safety and efficacy of a medical technology, whether it be a drug, device, or procedure.

Since the late 1960's, intraocular lenses (IOLs) have been used in the United States with increasing frequency as an alternative to eyeglasses and conventional contact lenses in restoring useful vision to cataract patients. The IOL, usually made of plastic, is implanted permanently into the eye during cataract surgery, following removal of the clouded natural lens of the eye. Although approximatley one-fourth of the estimated 400,000 cataract operations performed each year in the U.S. now involve implantation of IOLs, questions continue to be raised about the use of these devices. This conference provided a forum for discussion of IOLs by experts in ophthalmology and vision research, as well as representatives of consumer and professional groups. Following a historical review of intraocular lenses, seven panels convened to discuss the topics indicated below. In addition, studies of intraocular lenses either planned or in progress were reviewed, and organizations and individuals interested in intraocular lenses were given an opportunity to make public comment.

Lens Design and Manufacture

Since implantation of the first intraocular lenses by Harold Ridley, M.D., F.R.C.S., in 1949, these devices have undergone a continuous evolution in design, weight, and manufacturing process. Also, surgical techniques for inserting IOLs, and for cataract extraction as well, have been considerably refined during this time. However, the plastic material most frequently used in the optic or lens portion of such lenses—polymethylmethacrylate (PMMA)—has remained the same.

The panel on Lens Design and Manufacture considered lens materials currently used for the optic and haptic (loop) portions of the device, techniques of lens manufacture, quality control, and evaluation of the lens by the surgeon. The panel agreed that currently used lens materials, with the exception of metal loops, are generally satisfactory, although they may contain substances which influence tolerance. Improved tolerance should be one goal of future research. It is also

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NIH Consensus Development Conference Summary Vol. II.

EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

desirable to search for improved materials or coatings which minimize possible damage to the endothelium.

The panel called for industry-wide adoption of uniform physical and chemical manufacturing standards, and concluded that all current alternative IOL fabrication techniques are satisfactory, provided that stringent quality control is maintained. The panel called for continued cooperation among the research, manufacturing, and ophthalmic communities to improve further lens implant design and materials development.

Preoperative Evaluation of the Patient

The panel on Preoperative Evaluation of the Patient agreed that a careful examination of the cataract patient before surgery is important, whether or not intraocular lens implantation is planned. The results of the examination should be written into the medical record. For those who are to undergo lens implantation, careful slit lamp examination of the eye is imperative to rule out abnormalities that may contraindicate IOL implantation. In addition, there was a consensus that A-scan ultrasonography is of definite benefit in the preoperative examination. Although specular microscopy is also considered to be a valuable clinical and research tool, the panel said that it is not presently considered a routine part of the examination prior to primary lens insertion. The panel suggested that further studies to correlate maintenance of corneal clarity with endothelial cell count might help to clarify this instrument's role in predicting the development of corneal edema following lens implantation. Such studies were strongly recommended by the panel.

Indications and Contraindications for Intraocular Lens Implantation

The panel on Indications and Contraindications for Intraocular Lens Implantation agreed on broad general guidelines for ophthalmic surgeons who perform intraocular lens implantation.

The panel recommended that in general intraocular lens implants be restricted to the elderly, that they be implanted in the eyes of slightly younger patients only when contact lenses or spectacles are not likely to provide adequate visual function, and that they initially be restricted to one eye unless the needs of the patient dictate otherwise.

The panel also acknowledged other possible special indications for IOL implantation, as follows:

- Patients whose occupation may rule out contact lens wear;
- Elderly patients with an advanced cataract in one eye and visual acuity of 20/40 to 20/60 in the other eye, or exceptional patients whose activities are severely impeded by cataract even when better vision is present in the other eye;
- Slightly younger people with physical or mental infirmities who are poor candidates for contact lenses;
- Elderly patients with disabling cataracts in both eyes, in which case an intraocular lens may be indicated in one eye, and perhaps in the second eye if the patient cannot function adequately on a uniocular basis. A reasonable time period should elapse before the second operation.

Patients with bilateral macular degeneration are also possible candidates for intraocular lenses if they have dense lens opacities which would be expected to reduce their vision to less than 20/200. And, elderly individuals who wear a contact lens for unilateral aphakia, but require cataract surgery in the second eye, may be considered for intraocular lens implantation.

Contraindications to implantation of intraocular lenses are as follows, except under very unusual circumstances:

- The patient's desire not to have an implant;
- Axial myopia greater than 7 diopters;
- A poor result from an implant or cataract extraction alone in the first eye;
- A patient with only one eye with potentially good vision;
- A relatively young patient;
- Individuals with senile macular choroidal degeneration without dense cataracts in both eyes;
- Endothelial corneal dystrophy;
- Proliferative diabetic retinopathy and possibly significant background retinopathy;
- Uncontrolled glaucoma;
- Previous retinal detachment in either eye;
- Congenital cataracts (particularly rubella cataracts) and cataracts associated with certain other ocular abnormalities (such as recurrent iritis, essential iris atrophy, or atopic dermatitis);
- Significant complications during the cataract extraction procedure.

Method of Cataract Extraction

The panel on Method of Cataract Extraction agreed that there are circumstances under which either intracapsular or extracapsular extraction would be equally suitable for cataract removal in conjunction with intraocular lens implantation. Under certain circumstances, however, there may be a definite procedure of choice. To determine the specific indications for each of these methods, the panel recommended controlled studies comparing intracapsular and extracapsular cataract extraction in association with intraocular lens implantation. The panel also called for studies to determine the optimum timing and technique for discussion of the posterior lens capsule and for research on methods for preserving transparency of the posterior lens capsule after extracapsular extraction. In addition, the panel suggested that the precise relationship between various methods of cataract extraction and subsequent cystoid macular edema warrants further study.

Retinal detachment occurs more frequently after cataract extraction, with or without intraocular lens implantation, than in the population as a whole. Evidence concerning which method of cataract extraction combined with lens implantation carries less risk of retinal detachment is inconclusive at this time. Therefore, further study of this question is also recommended.

Experience to Date with Intraocular Lens Implantation

The panel on Experience to Date with Intraocular Lens Implantation summarized and discussed clinical experiences with intraocular lens implantation which have been reported by many investigators. Excellent visual results have been reported for each of a variety of intraocular lens types, and some insight has been gained regarding possible advantages and risks associated with each. It was the consensus of this panel that the use of intraocular lenses is associated with a small but significant risk of additional complications beyond that of cataract surgery itself. Many of these may be transient or treatable medically and thus do not affect the visual result.

The incidence of severe corneal decompensation leading to significantly reduced visual acuity is reportedly greater following lens implantation, and it may require subsequent corneal transplantation. But this condition is not distinguishable from that which follows cataract extraction alone, and its occurrence has been reduced considerably in recent years by refinements in surgical techniques.

Without disparaging published information on the safety and visual advantages of intraocular lenses, some of the panel members believe that prospective clinical trials are required to refine knowledge of both the short-term and long-term advantages and risks of lens implantation. One of the questions that may be studied in a controlled trial is the relative risk of cystoid macular edema and/or of retinal detachment in extracapsular versus intracapsular surgery, in the presence or absence of a lens implant. The panel also recommended continued study of a large series of matched patients being followed in Miami because this will provide at least a five-year headstart on any future prospective studies and important information on long-term visual results.

Special Considerations in Intraocular Lens Implantation

The panel on Special Considerations in Intraocular Lens Implantation discussed secondary implantation, bilateral implantation, and implantation in pediatric patients. The panel members emphasized that patients should be made aware of the additional risks involved in secondary and bilateral implantation. They concluded that there is presently a limited role for secondary implantation of intraocular lenses, and they recommended that secondary implantation be limited to older patients who cannot wear contact lenses or spectacles, specifically to persons who are incapacitated by unilateral aphakia and who have a particular personal or occupational need for binocular vision. Because late complications have occurred in the occasional patient with an intraocular lens, great caution is indicated in considering bilateral implantation. The panel agreed that contact lenses should be considered before deciding on bilateral implantation, and that bilateral implantation should not be used in young patients, except under unusual circumstances.

The panel also agreed that there were relatively few indications for lens implantation in children, although there is some feeling that an intraocular lens might be used in a child with a unilateral congenital cataract, but then only in a controlled clinical trial. Additional data from follow-up studies on children who currently have intraocular lenses should be made available and analyzed before there is any widespread use of IOLs in this age group. Well-controlled studies in pediatric eye centers are suggested for this special group of patients. Although preliminary data suggest a role for intraocular lenses in acquired pediatric cataracts, great caution should be exercised in this area. Generally, use of IOLs in these instances is not recommended, but a controlled clinical trial is indicated.

Alternatives to Intraocular Lenses

The panel on Alternatives to Intraocular Lenses considered the many difficulties inherent to the use of spectacles for correction of aphakia, although some recent improvements in spectacle lenses may have made them somewhat more acceptable both cosmetically and functionally. Panel members acknowledged both the advantages and disadvantages of conventional hard contact and soft contact lenses which are optically superior to spectacles but which may be difficult if not impossible for elderly persons and certain other individuals to handle. They also pointed out that over a period of years expected replacements for conventional or extended-wear contact lenses will cost more than the one-time cost of intraocular lens implantation.

Although extended-wear lenses are a potentially significant advance in the treatment of aphakia, not everyone can be or should be fitted with them. Although early data look promising, additional information is required on the long-term safety and efficacy of extended-wear lenses.

New surgical techniques to change the curvature of the cornea, for example keratophakia or keratomileusis, are also undergoing rapid development, and some studies are in progress. Advances in these surgical techniques are expected, as are improvements in contact lenses and intraocular lenses. Long-term follow-up data and additional research are required on all these alternatives to aphakic spectacles.

Studies Planned or in Progress

The Food and Drug Administration's (FDA) approach to monitoring the testing of intraocular lenses was determined in large part by a Congressional mandate which required regulation of the lenses and institution of an immediate study while not interfering with the availability of the lenses. In the FDA study, all intraocular lenses are treated as investigational devices. The first release of data will be made at the American Academy of Ophthalmology meeting in November 1979.

Two prospective studies on intraocular lenses supported by the National Eye Institute were described. One is a five-year study of the effects of intraocular lenses on the corneal endothelium. In patients undergoing extracapsular extraction, contact lens wear will be compared to intraocular lens implantation. The other is a long-term randomized prospective study comparing intracapsular cataract extraction with contact lens wear to intracapsular extraction with intraocular lens implantation and extracapsular extraction with intraocular lens implantation. The principal comparisons will be of corneal effects, visual acuity, and complication rates.

A study of the economic implications of intraocular lens implantation is the first economic analysis conducted under the auspices of the National Center for Health Care Technology. An attempt will be made to determine whether IOL implantation costs more or less than various alternatives.

Several projects of the American Intraocular Lens Implant Society were briefly described. They include studies on: inflammation, sterilization procedures, lens coatings, and new lens materials; anterior chamber reactions; intraocular lenses compared to contact lenses in patients undergoing bilateral cataract extraction; and IOLs that have been removed. A quality assurance program is also being developed.

Public Comments

Two speakers, an ophthalmologist and a representative from the Health Research Group, strongly criticized the current status of intraocular lens implantation. Although both stated they were not opposed to the implantation of well-made lenses in appropriately selected patients, they raised the following concerns:

- Overuse of lenses in patients for whom they were not indicated.
- Adequacy of information given to the patient about the risks as compared to the benefits of the procedure.
- Inadequately trained lens implant surgeons.
- Need for reevaluation of Medicare reimbursement of IOL implantation.
- Marketing of lenses of inadequate quality as evidenced by numerous IOL recalls by the FDA.
- The purported failure of the FDA study to provide valid data on lens safety and efficacy.
- Adequacy of data on lens safety generally, and lack of data comparing the safety of lenses made by different manufacturers.

Representatives from the American Intraocular Lens Implant Society responded to the initial speakers and emphasized the following:

- Criteria for patient selection for IOLs have been available and widely disseminated for many years.
- Many problems with lenses were first identified by members of the Society; thus lens implant surgeons alerted the FDA to the advisibility of some recalls.
- From a numerical standpoint, most recalled lenses were recalled because it was decided to exclude them from the FDA study, but they never became a problem for patients because they were never used.
- Meetings, courses, newsletters and telegrams are used to provide the latest information on IOL problems to practitioners.
- Training of surgeons and peer review are also concerns of the Society.

Another ophthalmologist in the audience emphasized his concern that guidelines for training of implant surgeons should be developed.

The last speaker, an ophthalmologist representing the Montana Foundation for Medical Care (a Professional Standards Review Organization), described how widely-agreed-upon criteria for intraocular lens implantation were effectively used in his state as a basis for peer review of implant surgeons. After observing a wide variation in indications and contraindications used by Montana lens implant surgeons, the PSRO established a committee for reviewing records of intraocular lens implantations. After the PRSO adopted and applied what they considered to be conservative criteria, practice patterns were found to have changed to conform to the peer review standards. This, according to the speaker, has resulted in improved medical care in Montana.

The chairman of the conference was A. Edward Maumenee, M.D.

Panel moderators were Henry M. Clayman, M.D.; Donald J. Doughman, M.D.; Norman S. Jaffe, M.D.; Herbert E. Kaufman, M.D.; A. Edward Maumenee, M.D.; Ronald E. Smith, M.D.; and Bradley R. Straatsma, M.D.

General Assembly Report

JOSEPH S. COATSWORTH

When the Connecticut General Assembly convened in early February, it was confronted with an inflation-ravaged state budget, ever-increasing citizen resistance to existing tax levels and the necessity of imposing yet another austerity program on the state's various government agencies and programs. Mindful of this concern with fiscal austerity, the Connecticut Hospital Association (CHA), developed its own *Legislative Program - 1980* to, first, reduce unnecessary levels of health care regulation (hence saving state tax dollars), and, second, to avoid proposing legislation which involved increases in state spending.

CHA's Legislative Program - 1980 was created to explain to Legislators precisely what they could do to improve Connecticut's burdensome regulatory climate; to focus the attention of health care providers on specific, *positive* legislative solutions to abrasive and unworkable regulatory controls; and to identify, by the reporting of roll-call votes, which legislators consistently voted for or against the legitimate needs of the state's health care community.

In addition to lobbying, CHA's Legislative Program involved each of the following three steps:

1. Creation of a List of 10 Priority Bills. This list, which was to become the heart of the program, was created from ideas and suggestions solicited from all segments of CHA's membership, including its Council on Government and Board of Trustees.
The subjects focused on through the 10 bills were:

PEER REVIEW IMMUNITY—this bill sought to protect the confidentiality of hospital medical review committee proceedings by exempting them from use as evidence in a court of law.

HOSPITAL CAPITAL EXPENDITURES—this measure sought to increase the Certificate-of-Need (CON) regulatory review threshold from $50,000 to $150,000 for capital projects.

UNRELATED CONDITIONS ON CON APPROVALS—this bill sought to prohibit the state Commission on Hospitals and Health Care (CHHC) from attaching conditions to their CON approvals which were unrelated to the actual project involved.

PHILANTHROPIC GIFTS—this measure prohibited the CHHC from directing or controlling unrestricted gifts, endowments, etc. and their income to hospitals.

MEDICAID CLAIMS PROCESSING—this bill sought to require the state to contract out the paying of Medicaid bills to providers so as to speed up the currently long process.

HOSPITAL INSPECTIONS—this bill required elimination of a hospital inspection now required by the state since it essentially duplicated one done on behalf of the federal government.

INSURANCE TRUST—here the goal was establishment of a malpractice insurance trust under the management of CHA so as to increase competition in this now highly restricted market.

SIMPLIFIED SUPER SCREEN—this bill sought to create a more objective standard, based on price increases, inflation and quality improvements, for hospital budget review.

FISCAL NOTES ON REGULATION—this bill sought to require a state agency wishing to promulgate a regulation to provide an estimate of the fiscal impact which the regulation would have on the industry involved.

ENERGY CONSERVATION PROJECTS—here the objective was to provide hospitals with a speedier review of their energy-saving projects so as not to jeopardize potential federal funding. This bill also covered projects mandated by the government such as those for occupational health and safety.

JOSEPH S. COATSWORTH, Connecticut Hospital Association's Vice President, Government Relations, Wallingford, CT. A veteran of five terms in the state legislature, he served as both Assistant Majority Leader and later as Deputy Speaker in the state House of Representatives. Mr. Coatsworth also has served as an officer of a major Connecticut banking corporation and as a private financial consultant.

2. Development of a Grass-Roots Communications System Between Health Care Personnel and Legislators. By encouraging hospitals to sponsor such activities as legislative breakfasts, as well as meetings between groups such as auxilians and legislators, CHA sought to help these groups get to know each other better, and to better familiarize the legislators with each of its 10 priority bills.

CHA also encouraged hospital administrators, physicians and trustees to maintain contact with legislators both by mail and telephone. Participation by other hospital employees in the process was also recommended.

3. Communication of All Legislative Action on CHA Bills to the Entire Membership. By keeping its members informed of all votes, CHA sought not only to show who was favoring or opposing the measures important to hospitals but also who deserved thanks for their consistent support. Thus, the recording of votes proved to be not only in the interest of CHA's members, but of the legislators as well.

How effective was CHA's approach? As the Assembly drew to a close in May, four of CHA's priority bills had been signed into law. Among these new laws was CHA's peer review immunity measure, the CON threshold bill and the one which provided for a more speedy review of hospital energy and government mandated projects. Also approved was the bill to eliminate the duplicate hospital inspection.

CHA's priority bill to protect unrestricted gifts to hospitals also passed both houses of the General Assembly, but was later vetoed by the Governor in what was widely interpreted as a retaliatory move by the CHHC for its own failures during the Assembly session. That veto was overridden in June.

The success of this year's approach to the General Assembly was due to the active participation of the health care community and the willingness of legislators to respond to genuine needs, properly presented. It is CHA's belief that citizens and interest groups have not only a right, but indeed, an obligation to present their views to their elected representatives. Such an obligation is especially important in light of the growing role of government in the shaping of hospital and health care policy both in Connecticut and the nation.

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PAC: Vehicle for Good Citizenship

MICHAEL P. LEVIS, M.D.

"Without the help of the medical community in my district, I would not have been elected to Congress."

This is an actual quote from Congressman George O'Brien (R-17) of Illinois regarding his narrow election victory in 1974 and his victories since that time. It is also the best thing that can be said about medical political activity by a candidate. It is AMPAC's hope to have victorious candidates throughout the United States saying the same thing.

Since AMPAC was formed in 1961, its purpose has been twofold: to educate physicians in sophisticated political activity and to help the physician spend his political dollar wisely.

AMPAC, the American Medical Political Action Committee, is the separate segregated fund of the American Medical Association. The term "separate segregated fund" is a term from the Federal Election Campaign Act of 1971 as amended in 1974. The 1974 amendments provided for corporations, associations and unions to establish and maintain political action committees.

AMPAC is much older than most political action committees. This is because in the early 60's physicians saw the need for concerted political action. Most state medical political action committees, which jointly raise funds with AMPAC, were also formed in the early 60's.

Here is how a political action committee works. The association solicits contributions from its members. The contributions are voluntary and are specified for political action at the state and/or federal level. AMPAC solicits contributions only for U.S. Senate and U.S. House races. Many state medical PACs solicit for those races as well as state legislative and other state races.

This kind of federated giving gives the physician a better opportunity for his political dollar. Many people ask why the physician can't just give his money directly to the candidate. AMPAC and the state medical PACs encourage individual giving. But they also encourage giving to the political action committee. Here is why. Consider a physician who lives in a congressional district where an unfriendly, but popular, incumbent is sure to win his current reelection bid. It would be a waste of the physician's political dollar to contribute to the incumbent or to the challenger. However, by giving his money to a political action committee, the PAC can spend that money in a race in some other district, perhaps in some other state, where a friendly incumbent is in trouble, or a friendly challenger is capable of beating an unfriendly incumbent. AMPAC spends its money wisely where it will do the most good. It avoids supporting sure winners and sure losers.

Michael P. Levis, M.D.

MICHAEL P. LEVIS, M.D., Chairman, AMPAC Board of Directors, AMA Delegate and member of the Pennsylvania Medical Society. Dr. Levis practices surgery in the Pittsburgh area.

There is another reason that political action committees give the physician a better opportunity for his political dollar. AMPAC, for the most part, supports candidates that are supported by the local medical community. Therefore, the physician who becomes active on the local level in the campaign sees his activities enhanced by contributions from AMPAC and perhaps his state PAC.

AMPAC has always believed that volunteer manpower in a campaign is as important as contributing funds. Therefore AMPAC encourages physicians and their families to give of their time as well as from their pocketbook.

Some of the ways in which AMPAC has trained physicians and their spouses to become active in campaigns include writing letters to their patients about the candidate, writing letters to people who live in their precinct about the candidate, serving on the candidate's steering and/or fundraising committee, raising money from other physicians for the candidate, providing volunteers for campaign headquarters, and serving in a variety of leadership positions for the candidate.

Physicians and their families are usually opinion makers in the community. AMPAC has always encouraged them to use this valuable asset on behalf of their candidate.

Doctors' wives play a valuable role in medical political activities. They can and do perform a variety of campaign services, especially in leadership positions. John M. Smith, Jr., M.D., AMPAC Board Secretary, has said that "Doctors wives have the potential of being the largest campaign work force in the country." From South Dakota to Texas, from Virginia to California, doctors' wives have played key roles in campaigns as well as providing rank and file volunteers.

In addition, physicians' wives serve in a variety of political party positions. Betty McCain is the state party chairman for the North Carolina Democratic party. Betty Heitman of Louisiana is the Chairman of the National Federation of Republican Women. Other physicians' wives serve as national committeewomen and committeemen for their own political party.

While AMPAC neither encourages or discourages physicians to serve in public office, there is right now a governor who is a physician, Governor Otis Bowen (R) of Indiana.

Four physicians serve in the current congress. They are Larry McDonald, M.D. (D-7) of Georgia; Tim Lee Carter, M.D. (R-5) of Kentucky; Ron Paul, M.D. (R-22) of Texas; and Delegate Melvin Evans, M.D. (R) of the Virgin Islands.

AMPAC is a bipartisam political action committee and as such supports candidates of both major parties. In addition, AMPAC supports the congressional, senatorial and national committees of both major parties. The leaders of both major parties, in return, support the concept of medical political action. They know that doctors working in political campaigns for candidates of their party can mean the difference between winning and losing.

AMPAC uses other criteria, in addition to local medical community support, to evaluate whether or not funds should be contributed to a candidate.

If the candidate is an incumbent, he has a better chance of winning due to the benefits of holding the office. Incumbency is the best insurance in winning an election.

AMPAC supports candidates in the following order: friendly incumbents who are in trouble: friendly candidates in an open race; and, friendly challengers to unfriendly incumbents. Also, if a candidate won his last election by less than 55% of the vote in a two-man race, that candidate is considered vulnerable to defeat and special attention is paid to such statistically marginal races.

AMPAC encourages individual physicians to use the same kind of objective political criteria in evaluating their local campaigns. And while medical and health issues are important to physicians, AMPAC encourages the medical community to base its support on the candidate's stance on many issues, as well as his or her suitability for the local congressional district. When AMPAC makes candidate-support decisions, it does not use commitment to health legislation as a criterion. Neither does it use party label or evaluation of a candidate's voting record.

When a physician or his spouse contributes to AMPAC, he usually contributes to a joint fund-raising PAC, called a state medical political action committee. There are two suggested categories of membership in AMPAC. One is an active membership ($10) and the generous category is the sustaining membership ($50). Contributions to the state PAC are over and above this amount.

Contributions to AMPAC are on an annual basis. Political activity is year-round and the term "election year" means merely that the election is held in that year. Since the Federal Election Campaign laws of the early 70's were passed, campaign financing is needed year-round and earlier contributions to a campaign mean much more than later contributions. The year 1979 was AMPAC's most active "off year" for election activity. In getting ready for 1980, AMPAC has already supported 162 congressional candidates for the 1980 elections. AMPAC contributed to 148 U.S. House candidates and 14 U.S. Senate candidates in 1979.

During 1977 and 1978, AMPAC supported 415 candidates for the 1978 elections. Of this number, 367 candidates were running for the U.S. House of Representatives and 48 were running for the U.S. Senate. Seventy-four percent of the candidates AMPAC supported in 1978 elections were successful.

For the first time, AMPAC made independent expenditures on behalf of candidates. AMPAC supported 16 House candidates and one Senate candidate through one-page ads in national magazines. In addition, AMPAC supported ten candidates by supplying county committees of the candidate's party with campaign buttons for distribution before the election.

This was AMPAC's first venture in this kind of expenditure. AMPAC moved cautiously in this experiment. Some political experts feel that independent expenditures, that is those expenditures made on behalf of a candidate but without his knowledge and consultation, may be the wave of the future for political action committees and other groups who support federal candidates.

Looking ahead to 1980 and beyond, AMPAC will continue to encourage physicians and their spouses to serve as delegates and alternate delegates in presidential nominating conventions beginning with 1980. Already, plans are being formulated for medical political participation in the Republican National Convention to be held in July in Detroit and the Democratic National Convention to be held in New York City in August.

In addition, AMPAC is acutely aware of the importance of congressional reapportionment and redistricting in the make-up of the U.S. Congress in the decade of the 80's.

The people who will serve in Congress in the 1980's will be determined, in large part, by state legislators and governors elected in the 1980 elections. Every ten years following the U.S. Census, congressional districts and legislative districts are reapportioned and redrawn in most states. According to projected statistics, some states, including New York, Ohio, Illinois, Michigan, New Jersey, Pennsylvania and South Dakota will lose seats in the House. States that will gain congressional districts include California, Florida, Texas, Arizona, New Mexico, Oregon, Tennessee, Utah and Washington. Changes may occur in other states. In addition to reapportionment, at least 40 states will redraw congressional district lines and probably all states will redraw their legislative lines.

Political activists should prepare for the loss of these districts by getting involved in legislative and congressional races right now in order to have an influence over the redrawing of your congressional district lines. Study your congressional delegation because by the time 1982 rolls around, two of those faces will be missing.

Continuing to look toward the 80's, AMPAC will continue its efforts to maintain and protect the integrity of the American electoral process. Surveys financed by AMPAC, but conducted by a non-biased survey research firm, show that the majority of the American people oppose using tax dollars to fund congressional campaigns. However, groups such as Common Cause and others continue to push for taxpayer financing of congressional campaigns. Here are seven reasons why AMPAC opposes taxpayer financing of congressional campaigns:

1. Taxpayer financing protects incumbents.
2. Taxpayers do not support the idea of using their tax dollars to fund congressional campaigns.
3. Taxpayer financing turns over the control of elections to bureaucrats.
4. Taxpayer financing erodes the traditional accountability which a congressman must have to his constituents.
5. Taxpayer financing makes elections unexciting and lowers voter turnout and communication.
6. Taxpayer financing erodes party responsibility.
7. Taxpayer financing forces the taxpayer to support candidates they do not like and do not want.

The number of political action committees are growing. AMPAC welcomes the growth of political action committees and will continue to help others establish and improve political action committee techniques. AMPAC is the second oldest national political action committee, second only to the AFL-CIO's COPE. Because of this fact, AMPAC will continue to act as senior statesman in the area of political action committee activity.

Guidelines for Short-Course Tuberculosis Chemotherapy

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE.
PUBLIC HEALTH SERVICE, CENTER FOR DISEASE CONTROL
ATLANTA, GA.

*The following recommendations on short-course chemotherapy for tuberculosis form a joint statement of the American Thoracic Society and the Center for Disease Control.**

Introduction

The objective of tuberculosis therapy is to achieve lifetime control of the disease for the patient. There are now available many drug regimens which offer virtually certain "cure" of tuberculosis. The primary factor which thwarts this promise of cure in the United States and other developed nations is noncompliance or failure to complete the prescribed regimen. Shortening the total duration of chemotherapy is a potential means of combating this problem. However, in choosing a short-course chemotherapy (SCC) regimen, consideration must be given to (1) assuring overall therapeutic success comparable to therapy of conventional duration, (2) avoiding any significant increase in drug toxicity, and (3) keeping the cost within an acceptable range.

Duration of Chemotherapy: Current State

Extensive experience with chemotherapy regimens of long duration has shown what results may be anticipated from them, even when accompanied by some irregularity or interruption in drug taking. Most patients apparently receive a quantity of medication sufficient to achieve an enduring cure.

A Public Health Service trial conducted in the United States has shown that daily isoniazid (INH) and rifampin (RIF) given for 20 weeks, followed by daily INH and ethambutol (EMB) until sputum has remained culture negative for one year, is an extremely effective and well-tolerated regimen.[1] Therefore, depending on the patient's initial bacteriologic status and therapeutic response, a treatment duration of no longer than 12 to 18 months can now be considered acceptable in the United States, provided that INH and RIF are given for at least the first 20 weeks. In those patients with obvious difficulty in adhering to self-administered regimens, directly supervised treatment on a daily or intermittent basis has been shown to enhance substantially the prospect for a successful outcome.[2] The reports of these regimens, which reflect results achieved under field conditions, should therefore serve as standards of successful outcome against which to measure SCC. An acceptable SCC regimen should allow reduction in the duration of therapy while resulting in a rate of relapse not greater than 5%.

The incidence of adverse drug reactions with the conventional-duration and supervised intermittent chemotherapy regimens is also quite low. Fewer than 5% serious drug reactions were reported with these drug regimens. Thus, to be generally acceptable, an SCC regimen should not entail toxic reactions above this level.

The fiscal comparisons are somewhat more difficult because of the "hidden" costs of tuberculosis care. In addition to the expense of the drugs, consideration must be given to the cost of hospitalization, cost of supervision of drug administration, and long-term medical, social, and economic consequences of inadequate or incomplete chemotherapy. However, unless there are vast differences in the cost, such considerations should be of secondary importance.

Short-Course Chemotherapy: Current State

Many of the published reports of SCC trial are difficult to evaluate because of (1) insufficient numbers of subjects in each treatment category to permit reliable conclusions with regard to relative effectiveness, (2) poor definition of the population studied, or (3) unclear criteria for exclusion from the study. Furthermore, in many of the published clinical trials, every dose of medication was administered under inpatient and/or outpatient direct supervision; thus, these results denote the best possible outcome obtainable with these drug regimens. Results obtained with direct supervision of treatment should not be extrapolated to a similar but unsupervised regimen. The proportion of drug doses that can be missed before a decrease in regimen efficacy occurs is unknown, but under routine program conditions, equally good results are not likely to ensue.

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* This statement was prepared by an ad hoc committee of the Scientific Assembly on Tuberculosis, and the Tuberculosis Control Division of CDC. The committee members are Michael D. Iseman, MD, Chairman, Richard Albert, MD, Matthew Locks, MD, James Raleigh, MD, Frank Sutton, MD, and Laurence S. Farer, MD (CDC).

A review of published reports of regimens of 6-month duration shows that most of them were followed by 5% or more relapses during 5 months' to 5 years' observation (3-9), and a few involved inpatient treatment for the entire 6 months.[3 4] For these reasons, a 6-month short-course chemotherapy regimen cannot be recommended for general use in the treatment of tuberculosis in the United States at this time. Regimens of this length are currently under study in this country and abroad and should be considered experimental.

Chemotherapeutic regimens in the range of 8 to 12 months' duration show more promise than the shorter programs. However, several regimens of this duration have shown either relapse frequencies greater than 5%[8 9] or unacceptable levels of drug toxicity.[9] Some of these regimens have given acceptable results but employed such drugs as streptomycin (SM) and pyrazinamide (which result in modestly increased toxicity, the inconvenience and administrative problems of long-term drug injections, and unpleasant subjective reactions to an extent which this committee would deem impractical for widespread and prolonged use) or thiacetazone (which is unavailable in this country).

It should be noted that the regimen of INH, RIF, SM, and pyrazinamide results in extremely rapid sterilization of tissues and that various combinations, durations, and rhythms of these agents[4 5 8 9 10] have proved highly effective. However, for the reasons stated above such drug regimens should not be employed universally; rather, they might be used in selected patients in whom there is a high probability of premature termination of treatment.

There are 3 reported SCC regimens that are most relevant to shortening the duration of chemotherapy in the United States. The British Thoracic and Tuberculosis Association (BTTA) treated patients with various regimens that included 2 months of INH, RIF, and SM or EMB, followed by 4 to 10 months of INH and RIF; all drugs were given daily and presumably self-administered except during the hospital period (duration not reported) and the SM injections.[6] The regimen that is of greatest interest is the 9-month therapy applied to patients with more extensive disease. In this group, all 135 patients showed good initial response, and no relapses were detected in 2 years' post-treatment observation. It should be noted, however, that a bias toward compliant patients may have operated in the enrollment for this study.

A variant on SCC was reported from Singapore by the British Medical Research Council. In this study, patients were given 2 weeks of daily INH, RIF, and SM; this was followed by 50 weeks of intermittent INH and RIF.[11] During the intermittent phase, the INH and RIF were given either once or twice a week, and the RIF was given either in 900 mg or 600 mg doses. The regimen that was composed of twice-weekly INH and RIF (600 mg per dose) was highly efficacious, well-tolerated, and relatively free of adverse effects.

The most extensive published domestic experience with SCC has been accumulated in the state of Arkansas, where a regimen of 1 month of daily INH and RIF followed by 8 months of twice-weekly INH and RIF was employed.[12] There were 10 initial failures among 185 patients and 1 relapse in the remaining 175 patients. The intermittent therapy was generally self-administered although those patients deemed significantly non-complaint were put on supervised drug administration. There were few instances of significant drug toxicity among these patients.

Based on these studies, the following generalizations regarding SCC can be made:

(A) INH and RIF given regularly for 9 to 12 months result in highly acceptable initial response and relapse rates among patients with drug-susceptible organisms.

(B) A substantial portion of this therapy may be given on a twice-weekly basis. This may be either fully supervised[11] or selectively supervised.[12]

(C) The initial phase of daily therapy may be as short as 2 to 4 weeks.[11 12]

(D) While SCC may prove effective in some patients with INH-resistant organisms, the overall response rates are not good enough to justify widespread use of SCC in this context.

(E) While there may be a modestly increased risk of toxicity with RIF given twice weekly, if the dose is proper the incidence of adverse reactions appears quite acceptable.[11 12]

Recommendations

Based on the foregoing considerations, the following recommendations for SCC in the United States are offered:

(1) A chemotherapy regimen using a "core" of INH and RIF for a minimum of 9 months' duration is an acceptable alternative to regimens now being used for adults with uncomplicated pulmonary tuberculosis. Although extensive data are not available for children, the regimen would probably be suitable for children as well. At this time, recommendations for shortened treatment cannot be made for patients with extrapulmonary tuberculosis, for drug-resistant cases, or for

patients with complicating medical conditions (diabetes, silicosis, or drug- or disease-induced immunosuppression)..

(2) For the initial phase of treatment, the patient may or may not be hospitalized, depending on the severity of symptoms, public health considerations of infectiousness, and the ability to ingest medications and provide self-care.

(3) Treatment for the adult patient should begin with INH (300 mg) and RIF (600 mg) daily. In children, give INH 10 mg/kg up to 300 mg and RIF 10-20 mg/kg up to 600 mg daily. EMB (15 mg/kg daily) should be added if the patient resides in or has emigrated from an area with a high level of initial drug resistance, or if a history of previous antituberculosis chemotherapy is obtained. Drug-susceptibility testing should be carried out under these circumstances because of the increased chance of initial drug resistance, especially to INH. If used, EMB should be continued until initial drug-susceptibility studies confirm susceptibility to INH and RIF. If resistance is found, a revision of the chemotherapy regimen and the length of treatment will be required.

(4) After an initial daily phase of chemotherapy ranging from 2 weeks to 2 months, treatment should be continued, employing either daily (if self-given) or twice-weekly (supervised) INH and RIF. If drugs are self-administered, adherence to the regimen should be carefully monitored by such indicators as clinic attendance, pill counts, urine tests, and bacteriologic examinations of the sputum. If a patient is judged to be unreliable in self-administering medication, therapy should be switched to directly administered, twice-weekly INH (15 mg/kg) and RIF (600 mg). Patients who are receiving RIF intermittently should be regularly monitored by history for possible manifestations of thrombocytopenia (purpura, petechiae, hematuria) or the "flu syndrome."

(5) Treatment should be continued for no less than 9 months and longer if necessary (until at least 6 months have elapsed from conversion of sputum to culture negativity). Since over 90% of the patients taking INH and RIF can be expected to become sputum negative within 3 months of starting treatment, total treatment for more than 9 months should be exceptional. If there are serious questions regarding the regularity of drug ingestion, if there have been complicating medical conditions, or if there is evidence of disseminated disease, it may be advisable to extend the duration of treatment even beyond 6 months of sputum negativity.

(6) Patients should remain under surveillance for 12 months after completion of therapy. This practice should be continued until sufficient data are accumulated to assure the efficacy of the SCC regimen(s) under field conditions in the United States.

Conclusion

The time has come for SCC regimens to be introduced in U.S. treatment programs with the stipulation that there be systematic collection of data for assessment of results under *program* conditions, among different populations, and in different geographic areas. Until such data have been collected and analyzed, it is advisable to observe patients who have received SCC for 12 months after stopping drugs, since most relapses are likely to occur in that period.

Close scrutiny of all patients on chemotherapy and directly administered treatment for noncompliant patients will enhance the benefits and minimize the risks of shortening treatment. Therefore, the available resources for patient supervision cannot be reduced and may even have to be augmented for SCC to be successful. With careful implementation and assessment, the introduction of SCC can represent a major step forward in tuberculosis treatment.

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A School Health Education Program

BENJAMIN M. SHENKER, M.D.

School health education has been a government mandate for many years. As yet there have been no coordinated mechanisms by which the quality of such a program is evaluated.

About eight years ago some supervisory personnel, teachers, and I in the capacity of physician director of the school health program, began the organization of an in-depth curriculum for all grades (K-12). Three people (unemployed teachers) were hired as health educators. Their initial task was to research a number of existing programs, derive as much information as possible, then put together a curriculum for the entire school system. These educators, working with an advisory group, accomplished the study in about one year and began implementation of their work the following school year.

The teaching guide, a moderately thick volume, covered practically every health topic, and was so organized as to present a carefully arranged group of subjects with the method of presentation adjusted to the grade level. Two years of experience convinced us that we had developed an unusually fine modus operandi. Periodic discussions were used to implement, adjust, or refine our methods. Certain conclusions were reached which we feel may be useful to other school districts where a health education program is being initiated or, if already in existence, is under consideration for modification.

Initially and most importantly, it was decided that the job of a health educator is to coordinate the program, to make available to teachers all resources (i.e., books, pamphlets, videotapes, special demonstrations, and guest speakers), to meet with individual teachers to discuss problems of interpretation and presentation, and to advise as to obsolescence of old material and sources of newer and better materials. The classroom teacher, not the health educator, presents the information to the children. The program is spaced throughout the school year. The preferred time per subject is recommended, but each teacher presents the material in his or her own way.

Of equal importance is adjusting the subject material to be presented to the school grade and making it uniform throughout the entire school system. Thus, any student who may change schools, as many do, will receive approximately the same general subject content at the appropriate grade level.

We have followed the concept of a totally balanced approach which impresses upon a child at the earliest age the importance of all aspects of health. As the student progresses through higher grades, the amounts of material and subject matter are correspondingly adjusted. No one health item is stressed excessively at any time. Program failure in the elementary school means even more obvious failure at the high school level. Every subject is presented in its proper perspective and in its relative importance to all others, whether it concerns smoking, sexual behavior, venereal disease, drug abuse, environmental hazards, proper food, sleep, and exercise, or tooth brushing.

As would be expected, the program involves relatively frequent checking, especially at the beginning. For this purpose an advisory board of approximately ten and eventually twenty people was formed. It included school administrators, teachers at various grade levels, a physician and dentist, a psychologist, and middle and high school students chosen by their classmates. Initially, meetings were held every one to two weeks, later four to six weeks.

Our apparently Utopian state began to have difficulties at the third or fourth year. As the City Council began to require greater economies of the Board of Education, our program somehow always seemed to become the first casualty, possibly based on the assumption that such a well organized system would be able to function just as well without the stimulus and

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expertise provided by the health educators. Within a period of four years we lost one, then two, and finally two years ago the third and last of our highly trained and very expert people. Two years we received a CETA funded person who adjusted to the work very well, but only just in time to be deprived of her funding and the job. Last year the classroom teachers did as well as possible to continue the program, but the level of efficiency became markedly lowered. It was obvious that strenuous efforts at revival were indicated. Within the past few months a new advisory group similar to the original but on a smaller scale has taken up the task. At the moment, no specific health-educator personnel exist.

To correct our deficiencies and prevent the almost inevitable loss of health educators at the first sign of a budget cut, we have finally obtained approval of the City Council whereby the health educator will be hired and paid by the city though the educational functions will be supervised by the school administration. The City will be financially committed to a maximum contribution which can be decreased by any monies obtained from federal or state grants.

This article has tried to summarize our experience in the field of health education, and list some conclusions which we considered important to derive maximum results. We have been able to contribute some of our hard earned knowledge to a few nearby communities at their request and have been pleased to learn that they too have found the material helpful.

A Summary of AMA, Medical and Health News

The medical profession won the long battle to prevent the Dept. of Health and Human Services from releasing a list of physicians who got Medicare payments in 1977. The Florida Medical Assn. and AMA filed suit in 1978, and in 1979 a U.S. District Court ruled that publication was unlawful. After a number of extensions, the final court date passed without an appeal and HHS asked for voluntary dismissal. The dispute goes back to March 1977, when the government released a list of physicians who supposedly received $100,000 or more from Medicare in 1975. An AMA survey showed an error rate of 65%. HHS (then HEW) apologized, but said it intended to publish another list. The AMA protested, saying that publication of the names of physicians and the amounts they received for services would be "an inherent violation of privacy" and would result in instances of "gross injustice."

A proposed amendment to marijuana legislation now before Congress, which would maintain existing criminal penalties for simple possession, may be too extreme, the AMA told the Senate Judiciary Committee. In a previous statement to the House Judiciary Committee, the AMA urged Congress to be "especially careful not to convey to young people and their parents the message that society now sanctions marijuana use." However, the Association expressed concern over "the stigma that any period of imprisonment or a felony conviction attaches to a young person's record and the lifelong barriers to many avenues of employment and other future development that may result from sporadic use of marijuana or even a moment of youthful misdirection." The AMA called for a middleground treatment of people found guilty of simple possession of marijuana and for severe penalties for those who traffic in the illicit marketing of controlled substances, including marijuana.

The AMA's Uniform Health Insurance Claim Form has been mandated by the Health Care Financing Administration for use in all Part B Medicare reimbursement and is the "preferred" form for use in the Medicaid program. The form was developed under the aegis of the AMA Council on Medical Service in cooperation with the Health Insurance Assn. of America and the Blue Cross and Blue Shield Assns. The form is being modified slightly for use in the Medicaid program. The current form will be used until the revised version becomes available about midsummer. The forms may be purchased through the AMA. For more information contact Dept. of Health Care Delivery Systems, AMA Headquarters, phone (312) 751-6395.

Model legislation defining death has been forwarded by the AMA to state medical associations. The model act states that an individual who has sustained irreversible cessation of circulatory and respiratory functions or irreversible cessation of functioning of the entire brain is to be considered dead, and that determination of death by a physician is to be made only in accordance with accepted medical standards. The model bill was adopted by the House of Delegates a year ago and was amended at the 1979 Interim Meeting. Legislation concerning brain death has been adopted by 25 states.

The background, recent activity, and AMA position on 21 "Health Legislative Issues, 1980" are detailed in a new booklet prepared by the AMA Division of Legislative Activities. Copies have been sent to state, metropolitan county, and specialty societies. Additional copies are available from the Dept. of Federal Legislation.

Marihuana Reexamined: Pulmonary Risks and Therapeutic Potentials

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Introduction

Two years ago the Council on Scientific Affairs reported on the health aspects of marihuana use.[1] In that report, adopted at the 1977 Clinical Convention, the Council warned of hazards associated with regular use by groups at high risk, including children, adolescents and persons with certain illnesses and disorders. The Council also alluded to possible therapeutic applications of marihuana and its constituents, and urged expanded research in this area.

At this time the Council reaffirms the findings, conclusions and recommendations contained in its previous report. Conditions today are basically the same as in 1977. The Council is aware, however, that since then concerns have been expressed, and some new data have appeared, regarding serious impairment of lung function and possible carcinogenic effects of heavy marihuana use. The Council also recognizes that there have been pressures to accelerate investigation into the therapeutic possibilities of marihuana, with a growing number of states permitting physicians to utilize the drug in clinical research contexts to treat patients who have glaucoma and those who experience nausea from cancer chemotherapy.

These two issues—the risk of pulmonary pathology including carcinogenesis, and the appropriateness of expanded clinical investigation into therapeutic uses—are therefore deserving of additional assessment and commentary by the Council.

There is a third issue, and that is the continuing trend, noted in the Council's 1977 report, of increased regular use by marihuana by youth. The latest data show that in 1977 there was a 25 per cent increase from the previous year in the number of 12 to 17 year olds who had ever used marihuana, and a nearly 30 per cent rise in the number of current users in that age group.[2] Of even greater import is the fact that there was a similarly marked increase among 8 to 11 year old children,[2] and that the cannabis preparations young people are taking today are generally more potent than those of three years ago.

Although pulmonary and certain other hazards of marihuana use have not been precisely determined, the greater likelihood of harm is for those persons who are in formative periods of physiological and psychological development. Regular marihuana use by children and adolescents may well result in long-term impairment and in disorders that can persist into adulthood.

Pulmonary and Carcinogenic Considerations

Bronchial and pulmonary irritation and other respiratory reactions to marihuana use have long been noted and well-documented.[3] More recently, interest has been focused on the possible additional damaging effects from smoking marihuana contaminated with paraquat, a herbicide sprayed on cannabis plants growing in Mexico. Toxic and lethal effects previously had been reported among workers using paraquat to spray weeds and clear land in Texas and California.[4] The possibility of chronic pulmonary toxicity certainly exists, but questions remain as to how frequently and to what degree it may occur. There has been, for example, no confirmed case of active interstitial fibrosis caused by the use of marihuana sprayed with paraquat, even though reserach supported by the National Institute on Drug Abuse (NIDA) suggests that heavy continuous use of such marihuana may be hazardous in this regard.[5]

Extrapolating from hamster studies, NIDA has speculated that smoking five or more paraquat-sprayed marihuana cigarettes a day for a year is likely to produce significant lung damage.[5] Although in these animal studies the paraquat was not burned before it was inhaled, that fact is not significant at high dose

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EDITOR'S NOTE: This report was prepared for the AMA Council on Scientific Affairs by an advisory panel consisting of Joseph H. Skom, M.D., chairman; Sidney Cohen, M.D., and David E. Smith, M.D. Rogers J. Smith, M.D., Council chairman and, at the time, vice chairman, participated in the discussions that formed the basis for the report to the House of Delegates at its meeting in December, 1979.

levels because a small portion of paraquat is typically not destroyed by burning. Moreover, even though most of the paraquat may be neutralized in the smoking process, bypyridine or other by-products of paraquat pyrolisis could have a possible role in infection of the respiratory tract, cough and hemoptysis.[6]

Alternative methods of taking marihuana, such as eating brownies, are no safeguard against paraquat effects. Paraquat concentrates in the lungs, regardless of the mode of ingestion.[5]

More studies are needed, however, particularly ones that can yield clinical data regarding humans, before definitive conclusions can be reached about long-term consequences of the use of paraquat-contaminated marihuana. The only adverse effect documented thus far has been the "paraquat panic" among certain users, following public announcement of the health hazards of spraying.[7]

With respect to carcinogenic potential, tobacco and marihuana leaf appear to be roughly equivalent.

Marihuana, because of its relatively poor combustibility, has up to 50% more aryl hydrocarbons (AHH) in its smoke than tobacco does.[8] (High levels of these hydrocarbon by-products are associated with susceptibility to bronchogenic carcinoma,[9] although it should be kept in mind that there are individual variations in the enhanceability of AHH in the lungs.)

Cigarette for cigarette, the difference between tobacco and marihuana may be even more significant because of the way marihuana typically is smoked—down to a miniscule butt—and because the smoke itself is retained in the lung for a longer period than tobacco smoke. Offsetting this higher "per cigarette" risk is the fact that most regular users of marihuana consume far fewer cigarettes than inveterate tobacco smokers do.

In one study, mouse skin painted with marihuana smoke particles produced metaplasia of the sebaceous glands;[10] in another study, tobacco tar applied to the skin of mice proved to be more carcinogenic than marihuana tar.[8] Although the implications for humans are not clear, combined use of tobacco and marihuana can be expected to increase carcinogenic risk. In one of the few human studies comparing adverse effects of cannabis and tobacco, bronchial biopsies revealed basal cell hyperplasia and squamous cell metaplasia to the greatest degree in subjects who used both tobacco and hashish, to a lesser degree in those who smoked only tobacco or hashish alone.[11]

Neither the prevalence nor the degree of combined tobacco and marihuana use has been assessed. One study of more than 9,000 high school juniors and seniors in ten cities, conducted in the spring of 1974, showed that 57% of those who used marihuana as their only drug smoked at least one tobacco cigarette a day, as did 73% of poly drug users—those who used marihuana and one or more other drugs.[12]

It would be advisable to devote additional research efforts to the effects of heavy and chronic combined use—five or more marihuana plus ten or more tobacco cigarettes per day—and the extent of such use, especially among children and adolescents.

Therapeutic Considerations

Some clinical evidence, as well as anecdotal reports stemming from attempts at self-medication, have ascribed several therapeutic benefits to marihuana and its constituents.[13] They include bronchodilation for asthma attacks, decongestant action for symptoms of the flu, antispasmodic effects in paraplegia, reduction of intraocular pressure in glaucoma, and antiemesis in the treatment of nausea associated with cancer chemotherapy. Marihuana also has been variously viewed as a possible sedative, antianxiety agent, and analgesic.

At present marihuana has no officially accepted medical use, and is classified in Schedule I of the Controlled Substances Act. Some 13 states, however, have passed laws permitting physicians to prescribe marihuana for certain indications, principally glaucoma and cancer-related emesis, under broad research protocols.[14 15] The quality of such research is questionable, however, because physicians in private practice usually are not in a position to conduct adequate double-blind cross-sectional investigations. In most cases, they are providing treatment responsive to users' self-reports of beneficial effects, under a research guise necessitated by requirements of federal law.

Carefully designed animal and human research should concentrate on the two most promising medical applications—for emesis and glaucoma. Among important issues waiting to be addressed are the following:

1. Which of the nearly 300 constituents of marihuana, in addition to delta-9 tetrahydrocannabinol (THC), are of therapeutic value?
2. Can the euphorogenic effects of marihuana be isolated and eliminated in order to reduce the abuse potential for persons taking the drug for therapeutic reasons, and is there a role here for derivatives and synthetics?
3. Can antiemetic effects of marihuana be maximized by combining it with drugs now in use for this purpose?
4. In the treatment of glaucoma, what is the degree of tolerance to marihuana's ocular hypotensive effect, what is the drug's effectiveness in topical form, and how does it interact with other antiglaucoma medications?
5. What are specific contraindications for the use of marihuana in therapy (e.g., persons with ischemic heart disease)?

As research is intensified, and as more states pass laws that facilitate clinical investigations, the problem of securing marihuana of uniform good quality could become acute. The government-authorized "marihuana farm," located in Mississippi, is the only source of unadulterated marihuana of predetermined potency. It may become necessary to place additional acres under cultivation, so that investigators are not forced to turn to less desirable sources of supply; marihuana that has been seized by enforcement agents is one source that has been sanctioned and is being utilized in at least two states.[14]

Conclusion

As possible therapeutic agents, marihuana and its derivatives will be subjected to careful scrutiny for untoward side effects, adverse reactions and contraindications. The public may then come to realize more fully what pharmacologists have known all along: that marihuana, as any other drug, has potential for harm as well as for good, and that the traditional triad of dose size, duration of use and makeup of the user is a highly appropriate touchstone for evaluating its risks and benefits.

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Confidentiality: Attorney-Physician Relation

The patient's history, diagnosis, treatment, and prognosis may be discussed with the patient's lawyer with consent of the patient or his lawful representative. The physician has obligations to society as a whole in addition to his obligations to his patient as an individual. In many instances, the peculiar knowledge and attainments of the physician are indispensable to patients or others in the administration of business and government and in the usual conduct of certain daily affairs. When this knowledge, acquired during the course of the physician-patient relationship, is necessary to enable the patient to obtain his just due the physician should make it available for the patient's benefit under proper conditions. Discussion with or report to the patient's attorney may be proper and necessary in order for the patient to perfect a claim. The attending physician may ethically discuss such matters with the attorney providing, of course, that the patient has consented to the discussion.

It is not improper, in and of itself, for a physician to testify in court or before a workmen's compensation board or the like in any personal injury or related case.

—Opinions and Reports of the Judicial Council of the AMA

Month in Washington

Despite the insistence of the Food and Drug Administration that there is no lag time in the approval process for new drugs, the U.S. General Accounting Office has declared the drug lag official.

In a recent report entitled "FDA Drug Approval—A Lengthy Process That Delays the Availability of Important New Drugs," the GAO said that for some important drugs (those providing a major or modest gain over any other marketed drugs), the approval process delays the availability of the therapeutic benefits a drug may provide to the public."

The report found that during one particular period—July, 1975 to February, 1978—the FDA approved 14 significant new drugs, 13 of which had already been approved abroad. Norway, Canada and Switzerland approve new drugs on an average of one-half the U.S. approval time, while England averages one-fifth the U.S. approval time.

The GAO Report did not reserve all its criticism for the FDA. Industry must also share the blame for a slow approval process. The report charged that drug companies submit incomplete new drug applications and are slow to resolve deficiencies. The FDA is responsible for other major delay factors including:

- scientific and professional disagreement between FDA and industry.
- imprecise FDA guidelines, subject to varying interpretations.
- slow or inadequate FDA feedback to industry and lack of promptness in notifying drug firms of deficiencies in applications.
- limited time spent reviewing an uneven workload.
- lengthy chemistry and manufacturing control reviews.

"Other (delay) factors include intense congressional and consumer scrutiny of the drug approval process, adversary relationships between FDA and the drug industry, and FDA's conservative approach to drug regulation," said the GAO Report.

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The troublesome ethical and economic problem of providing heart transplants as a Medicare benefit will be weighed by a special study at the HHS Department.

Meantime, the Agency is halting the benefit which had been granted on an ad hoc basis for Medicare patients receiving transplants at the Stanford University Medical Center which performs about 25 transplants annually.

Medicare has financed a total of 23 transplants over the years. Heart transplantation has been developed at Stanford under Norman Shumway, M.D., into a procedure that has shown promise of greatly extending life.

HHS Secretary Patricia Harris told a news conference that "it is the promise of the extended life this new technique offers those facing death, along with the prospect of its increased use in future years, that makes the Department's policy decision in this area a matter of critical interest to the American public."

There are too many unanswered questions to justify a final decision on general Medicare coverage, Harris said. These include the patient selection process, the long-term social, economic and ethical consequences of the procedure, and the potential for national expansion of the heart transplantation procedure.

New medical techniques and technologies "demand that we develop a rational process that makes it possible to define what constitutes 'reasonable and necessary' medical services which can be funded by Medicare in the case of heart transplants and other procedures," she said.

The Department's two-year study will be conducted by the Health Care Financing Administration in cooperation with the Public Health Service's National Center for Health Care Technology.

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The HHS Department is sending a catalogue of comparative price information on 184 prescription drugs to all physicians and pharmacists.

The catalogue divides 184 of the most frequently prescribed drugs plus aspirin and acetaminophen into 16 therapeutic categories such as analgesics and anti-infectives.

Under each category, the guide lists the generic and trade names for each drug, the marketer of the products, and the cost to the pharmacist of an amount equal to one day of therapy of each drug. Bar graphs show the daily therapy cost of each drug relative to other brands of the same drug.

The guide is intended to help physicians and pharmacists consider the cost of different drugs when they write or dispense prescriptions, HHS said.

HHS said about half of the drugs commonly prescribed in the U.S. are available from multiple sources—

Prepared by the Washington, D.C.
Office of the American Medical Association

by both brand and generic names—and at widely varying prices.

Current statistics show that only 12 percent of written prescriptions specify the generic names of a drug.

Pharmacists are allowed in 35 states to dispense lower priced generic drugs in place of brand name products without the consent of the physician unless the physician indicates that the patient needs the higher priced brand.

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The American Medical Association has urged the Democratic Party Platform Committee to direct more federal effort toward the support of the private sector in order to strengthen the quality and accessibility of medical care for all Americans.

Testifying before the platform committee in Washington, AMA Chairman Lowell Steen, M.D., said the private sector is best equipped to take the lead in these activities with the role of the government limited to a supportive one.

The Platform should include a strong statement urging the elimination of unnecessary federal regulation in medicine, Dr. Steen said.

Noting that the medical profession is not opposed to all regulation, he said that any regulation attempting to dictate physician medical judgment and practice must be avoided. Any interference with the physician-patient relationship and the confidentiality of this relationship should be opposed, he added.

The AMA recommended that the Platform call for reforms in the regulatory process and that federal agencies be more publicly accountable for their activities.

A key proposal was that the Platform call for increased efforts to improve the nation's health status. "Included should be continued support for medical manpower and health care facility development, with increased research in the basic medical sciences. Special efforts should be concentrated in areas of health education for all individuals."

The Democratic Committee was asked to recognize the Voluntary Effort (VE) initiated by various private sector parties as the most effective and appropriate means of meeting hospital cost issues. "It has succeeded in holding down the rate of increase," said Dr. Steen.

"The AMA has also called on individual physicians to hold down fee increases, and the success of this effort is evident from the fact that the physician fee component of the Consumer Price Index during the past year was significantly below the 'All Items' element. We urge the Democratic Party to include in its Platform support for the VE as the best means of controlling the health care inflation."

The Platform should emphasize support to private sector efforts to improve health insurance coverage and protection, especially against catastrophic illness, said Dr. Steen. Improvements also should be sought in Medicare and Medicaid to assure mainstream medical care he added. The overwhelming majority of the population has coverage for medical services, but there are still gaps in coverage. "However, those problems do not necessitate a radical restructuring of the health care delivery system, such as is proposed by the President or by Senator Kennedy in their National Health Insurance plans."

The AMA Chairman said, "We reject the notion that, to meet the challenges of tomorrow, we must scrap the success of yesterday and today. Private health insurance has been a successful vehicle to opening the access to medical care for the vast majority of our population. We believe that the private sector can, in cooperation with the federal government where necessary, close the remaining gaps in insurance coverage."

Further, the Democrats should include in their Platform a call on the federal government "to keep its promise to the elderly and the poor—that Medicare and Medicaid eliminate, not perpetuate, financial barriers to mainstream medical care."

In concluding, "We believe the challenges of the '80s are to maintain and improve the quality of medical care and to ensure continued access to that care for all citizens."

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A middle-ground treatment of people found guilty of simple possession of marijauna has been urged by the AMA.

A substantial reduction in penalties might be interpreted (particularly by young people) as societal approval of marijuana use, the AMA told the Senate Judiciary Committee, but the maintaining of existing criminal penalties may be too extreme.

"We believe that a middle ground between the stiff penalties permitted under the current law and those proposed in S. 1722 (A bill before the Committee) would be more appropriate," wrote James H. Sammons, M.D., AMA Executive Vice President. "We are particularly concerned by the stigma that any period of imprisonment or a felony conviction attaches to a young person's record, and the lifelong barriers to many avenues of employment and other future development that may result from sporadic use of marijuana or even a moment of youthful misdirection."

Dr. Sammons said severe penalties should be kept for those who traffic in the illicit marketing of controlled substances, including marijuana.

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Nine national organizations in the health field, including the AMA, expressed concern to Congress about a proposal to make chiropractic education eligible for federal aid.

The proposal has been advanced by Sen. Harrison Williams (D-NJ), Chairman of the Senate Labor and Human Resources Committee, as part of the overall health professions assistance package.

The eight additional organizations are: the American Association of Dental Schools, the Association of American Medical Colleges, the American Association of Colleges of Pharmacy, the American Association of Colleges of Osteopathic Medicine, the American Dental Association, the American Pharmaceutical Association, the Association of American Veterinary Medical Colleges and the American Veterinary Medical Association.

In a letter to Committee members, Sens. Edward Kennedy (D-MA), and Richard Schweiker (R-PA), the organizations said:

> "We are concerned over, among other things, the timing of this development and the impact it may have on the existing programs under Titles VII and VIII of the Public Health Service Act. That is, at a time when all segments of health manpower are being asked to accept across-the-board cutbacks . . . it would seem a little inconsistent to simultaneously expand the base of eligibility and participation.
>
> ". . . it further troubles us that a proposal to establish entitlement for a new health provider group such as chiropractic would come without any of the normal legislative deliberations to which the Committee has customarily adhered. Indeed, without any recommendations from the Administration, any public hearings, and in general any of the close scrutiny which each of our professions has undergone before being covered under the Act, a very significant and major dilution of the program has been announced in this instance as almost a consensus modification.
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> ". . . if there is now an appropriate place for chiropractic or any other discipline within the Health Professions Education and Distribution Act of 1980, there should be no difficulty in substantiating it through a full and complete evaluation."

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The Carter Administration has taken a quick step backwards in its proposed directive to limit federal support for hospital construction. In the space of a day, White House officials withdrew from the proposal a provision that state and local health planning agencies would review and comment on proposed federal hospitals.

American Hospital Association President J.A. McMahon said that the change of mind makes the entire program "all the more political. They pulled back the only thing in the proposal that made any sense."

McMahon speculated that pressure from veterans' groups was responsible for the White House reversal. "They (the White House) didn't want to take on the veterans in an election year," McMahon said. An American Legion spokesman confirmed that a strong protest was lodged at the White House against inclusion of Veterans' Administration facilities in the health planning process.

Later in the month, however, the White House Office of Management and Budget (OMB) published in the *Federal Register* a proposed memorandum that would establish policies and procedures under the Carter plan to limit federal support for hospital construction in overbedded areas. The OMB document includes background data, definitions, and outlines of the policies and implementation procedures for hospitals.

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Insisting there were no political strings attached, the Administration has signed an agreement with New York State and New York City providing federal funds to keep open two Harlem hospitals slated for shutdown.

Under the agreement the federal government will spend $7.7 million to establish a Health Maintenance Organization at Metropolitan Hospital. The city and state together will contribute a similar amount.

In addition, the federal government will provide an unspecified amount to establish a specialized alcohol, drug abuse and mental illness program at Sydenham Hospital.

Both hospitals had been slated for closing by the city. They will remain open with the new federal programs.

"Metropolitan Hospital will become 'family doctor' to the people of the community," Patricia Harris, Secretary of the Health and Human Services (HHS) Department, said. "If this demonstration is successful, at the end of five years we will have a model delivery system which can be used by other inner city areas with similar problems."

The city plans to enroll at least 17,000 city workers and others with health insurance in the program, giving it a stable base. Mrs. Harris insisted there were no political strings to the agreement. "This is not, as some have said, an attempt to buy votes," she said. "The votes of the people of New York are not for sale."

Confronted by the first of a series of hospital closings in New York City last year, Mrs. Harris took a tough stand, insisting it wasn't federal government's responsibility to bail out failing hospitals. Ironically, New York State has a tightly regulated hospital system which federal planners often cite approvingly for keeping a lid on rate increases.

The agreement was signed at an elaborate White House ceremony featuring Mrs. Harris, Vice President Walter Mondale, New York Mayor Edward Koch and lawmakers from the state.

The President's Page

In response to a resolution of the House of Delegates, the Council on Medical Service of the A.M.A. has presented a study of Health Maintenance Organizations.* Some 183 pages in length, the study provides the basis for an excellent report by the Council. It will be of interest to all physicians as well as those now involved, or about to become involved, in an HMO.

The report examines in some detail fifteen recent fairly large HMO's of the staff, group and I.P.A. types and reviews some twenty years of related literature. Each of the summaries on the selected HMO's is informative. Unfortunately, information about the larger HMO's in existence for longer periods of time is not included under the assumption that knowledge of these organizations is readily available. More descriptive information on these and on California's Prepaid Health Plans and the other 188 HMO's would have greatly increased the value of the report.

Fifty-six pages are devoted to review of HMO performance based on the literature. Of particular interest is the section on cost of care. The study finds a reduction in costs to members of from ten to forty percent in all three types. Savings result from a marked reduction in hospital utilization as compared to the Blues. Undoubtedly, this is the strongest argument for HMO's and is worthy of more serious study. It is not surprising, since the greatest weakness of the Blues has been the strong financial incentives to overuse of hospitalization. The literature analyzed indicates that the reduction in hospital use is largely due to more readily available ambulatory care, although ambulatory care is probably more costly than in other health delivery methods.

The limited literature in the difficult area of quality of care is reviewed, including requirements for quality assurance, peer review, malpractice, outcome, and patient satisfaction. This is a very subjective area in which convincing evidence is not yet available.

Absent from the report is any significant discussion of regulation and control. Subsidies and loans are briefly described. Most of the fifteen models have relied heavily on government funding.

The study dismissed in two paragraphs the ethical questions created by physician incentives and the many questions concerning patient's rights and controls.

The subject of "health maintenance" or preventative medicine received little attention. The study indicates that preventative medicine is not emphasized in the groups studied and is not significantly different from that in other forms of practice and does not contribute to cost reduction.

The report will not change many opinions about HMO's or allay fears of extending government control. Uneasy about diminishing concern for ethical restrictions on physician-patient relationships, distrustful of increasing government controls, and not convinced of the cost effectiveness and quality of practice in HMO's, physicians are understandably unenthusiastic. However, the well documented reduction in rates of hospitalization with resulting reduction in cost of care should motivate organized medicine, the Blues, the insurance industry, and Medicare-Medicaid to examine more closely the present incentives and payment systems which promote greater hospital utilization.

W. Raymond James, M.D.
President

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*"Health Maintenance Organizations," American Medical Association, Council of Medical Service. Distributed to The House of Delegates, July, 1980.

Reflections from the Dean's Office

New Notions from Old Ideas

ROBERT U. MASSEY, M.D.

There is a tyranny in climates of opinion just as there is tyranny in democracy. It is easy to be deceived that we are thinking something quite new when, in fact, our thoughts arise from the same assumptions that everyone uses. It takes an effort to wrench ourselves free from 1980 even when we are paying attention to 1628 or 128.

Harvey and Galen lived in worlds whose assumptions were different from each other's and far different from ours. To understand what they wrote, we need to reach across the centuries and assume what they assumed.

I recall a medical historian trying to bring to life the old Greek concept of humors which had been the ground of medical thinking for twenty-two centuries. He talked of black bile, yellow bile, blood, and phlegm, making us see that these complex solutions and suspensions were simple concepts, not unrelated to our notion of temperament. He said that there was a correspondence between the four humors and the four elements: earth, air, fire, and water; and that these in turn related to the four cardinal properties: dryness, coldness, warmth, and wetness. We speak of dry humor and good humor, sanguine nature and melancholy. If somehow we could get inside the Greek mind that made these assumptions, we might understand how this system of fours survived for over two thousand years and how we got from Galen to Harvey and finally to modern molecular biology.

Of course we can go back so far in time or to a culture so unlike our own that we can make no connection except across the common ground of myth. The danger is that we then begin to impose our own assumptions on ideas where they cannot possibly fit. I suspect the social scientists and anthropologists do that more often than they know. One assumption coming from the Enlightenment is that there is social and artistic progress which more or less parallels scientific progress; there is the unspoken assumption that we are really smarter, more liberal, and less neurotic than our ancestors.

Peter Gay, in an article on Victorian mores, writes:

> "To proclaim instant candor as normal and reticence as pathological would be to impose the uncertain (and in many ways unpleasant) ideals of the 1960s and 1970s on the world of a century ago, and hence to be unhistorical in the extreme."[1]

We are forever revising history to suit our assumptions. The climate of opinion exercises its tyranny over us. Our 17th century European ancestors covered the interior of their Gothic churches with baroque ornamentation; now their descendents take down the baroque to uncover the Gothic. The Germans even have a verb for that activity, and declare that the building has been *gotischt.*

C.S. Lewis in defending some of the indirect values of liberal learning wrote:

> "Most of all, perhaps, we need intimate knowledge of the past. Not that the past has any magic about it, but because we cannot study the future, and yet need something to set against the present, to remind us that the basic assumptions have been quite different in different periods and that much which seems certain to the uneducated is merely temporary fashion."[2]

The present, with what Lewis called its "great cataract of nonsense," overwhelms us. Summer is a time to change our habits of reading; to read slower and read only those books which we like to believe we have read but know that we may have started and never finished.

Everyone has his own list which is best kept secret; we can always say that we are setting out to rediscover old friends. Chaucer's *Canterbury Tales,* Dante's *Inferno, Purgatorio,* and *Paradiso,* the Book of Job, or Goethe's *Faust* might qualify for someone.

We may have found them hard going because they are out-of-date. Enjoying them means making an effort to adopt for a while a whole new set of assumptions, but assumptions that taken together make sense. That is different from reading them as fairy tales where everyday reason can be suspended for an hour or two. Dante was using everyday thirteenth century reason and it made as much sense to him as ours does to us.

Some of the art and science of medicine still rests upon old assumptions that come clear only when we read something separated from us by centuries. It may not help our practice, but encountering unfamiliar humors and finding something in our own experience that helps us to understand them can be a pleasant summer pastime.

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Beyond the Adversarial Relationship: The Lawyer as Physician's Consultant

JOSEPH M. HEALEY, J.D.

The relationship between lawyers and physicians, even during the best of times, is touched by some degree of misunderstanding, suspicion, frustration, and even resentment. In an era such as ours, in which the law is pervasively involved as a regulator of the health care process, the degree of tension runs very high. In some areas, the result has been the construction of a barrier between the two professions which reduces the possibility of cooperation in addressing the unfinished agenda of medico-legal problems. As an attorney deeply involved in medico-legal issues, I am greatly concerned by this. Of equal concern, however, is my fear that this barrier often prevents physicians from using legal counsel in a positive way as a way of eliminating or reducing areas of potential liability. This underappreciation and underutilization of the law as a source of preventive strategies needs serious examination by physicians in light of the potential benefits available.

No single professional could possess the training, expertise and current knowledge of all aspects of the health care process to be able to deal effectively, alone, with all aspects of medical practice. This is especially true of legal aspects. Many medico-legal problems brought to my attention are in large part the result of inadequate anticipation of potential legal problems, nonexistent or inadequate practice policies designed to address those problems, or inaccurate understanding of legal responsibilities. It is my belief that physicians can reduce areas of potential liability by using the law and legal counsel in a preventive manner: by identifying areas of one's practice in which general or specific legal problems could exist; by developing with legal counsel practice policies tailored to their specific practice setting which address the areas of potential liability; by communicating these policies to one's partners, colleagues and employees, in the practice setting; and, by reviewing the policies and any incidents which have occurred on an annual basis, to permit changes and the integration of new developments in the law into revised policies. A major goal of such a program is to reduce the number of situations in which a practitioner is faced with unanticipated problems where action is not preceded by careful analysis of legal rights and duties and the development of strategies. How many physicians have carefully considered and carefully developed policies, applied in a manner consistent with the current legal status of the rights and duties involved in such areas as: (1) the follow-up and recall of patients with serious problems who are non-compliant or who miss appointments; (2) the authority of a minor to consent to treatment without parental approval; (3) confidentiality; (4) the refusal of medical treatment by a patient; (5) the management of office emergencies; (6) the allocation of responsibility to non-physician health providers? Yet any one of these areas could be the source of serious legal problems.

The positive use of the law as a preventive strategy would not guarantee that legal problems would be eliminated. No such guarantee exists. But the process of anticipation and policy formulation would unquestionably leave a physician better prepared to keep legal problems in proper perspective. Further cooperation between physicians and lawyers of this positive, preventive nature might also improve the relations between these two great professions who share a common responsibility to serve the community with their respective skills. The bitter barrier has remained too long. We need to move on to the major unanswered medico-legal questions.

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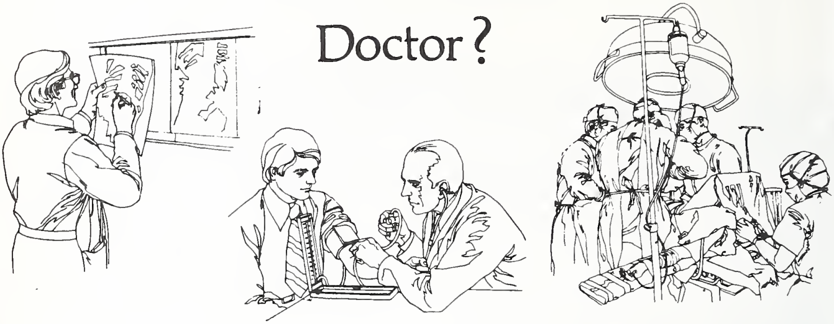

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EDITORIALS

Laboratory Medicine—1980

In the 16 years since I last served as guest editor for a Laboratory Medicine issue of *Connecticut Medicine* there have been enormous changes in the field, too extensive to detail in a single issue. An exponential increase in the total number of tests done has been accompanied by a corresponding improvement in their quality, so that the problem of "errors" is much smaller. This improvement has resulted from advances in instrumentation, reagents, laboratory management and personnel training. Some of it has been an indirect effect of Federal and State legislation and regulatory activities.

For this issue we decided to concentrate on a few specific areas in the forefront of pathology progress with emphasis on how these advances help our clinical brethren. The first two articles, by Otis and Smith, describe the diagnostic impact of relatively atraumatic procedures in the definitive diagnosis of lung diseases. The third article, by Lieberman and Lowell, indicates how newer biopsy and cytology procedures permit accurate evaluation of gastrointestinal diseases. Following this Kashgarian discusses the contribution of electron microscopy to diagnosis and how markedly it has advanced in the last 15 years. He estimates that 4% to 10% of all surgical specimens may be analyzed more effectively if electron microscopy is employed. In our final article in the field of Anatomic Pathology Nelligan makes a long overdue plea for a return to basics by greater reliance on autopsies. The autopsy is the final arbiter of diagnosis, of treatment, of new diseases, of the quality of medical care. It is remarkable how the autopsy has been increasingly neglected in an era when Quality Control is so heavily emphasized.

Following this Breakell reports on the progress of computers in laboratory medicine. The computer is a necessary complement to the vast amount of data we now generate; 77% of Connecticut Hospitals expect to have laboratory computer systems by 1983.

Finally McKinley, Taylor and Sangree present a case report of Campylobacter infection. This organism, unfamiliar to most of us, seems to be the commonest cause of bacillary diarrhea in Connecticut in 1980, and can only be found through newly available cultural techniques.

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Chairman of Pathology
Norwalk Hospital

Continuing Medical Education—The Arubascam

Long before there was Abscam we had Arubascam. In Arubascam the place of the Arab sheik is taken by a glossy folder showing a Caribbean beach, sunshine, the promise of extraordinary food, and a few glossy, nubile girls. It is as if nobility of learning were somehow dependent upon nubility of the flesh. There are usually the names of two or three famous medical personalities well known for their brilliance on the circuit. Casually mentioned at the bottom is that, in the best advice of counsel, the part of the trip which is devoted to education will be tax deductible under the guidelines of some statute or other. Also mentioned is the number of such trips you are allowed per year before you will be challenged by the Internal Revenue Service. Then, in bigger figures, are the magic numbers of CME Credits, Category I!

One of the chief charms of such a voyage is that American faculty and American physician students will travel together, often on the same plane or ship. Possibly these teachers and these students cannot teach and learn unless exposed to bright sunshine and white sand.

Arubascam is not meant to be particularly offensive to one site. It is a generic term for the education that now comes from the CCU (Caribbean Cruise University).

Part of the education is truly startling. Among the things the participants learn quickly is that the picture of the cruise ship's swimming pool on the brochure makes the pool look as if you actually could dive in and swim a couple of laps. The discovery of the actual postage stamp size of the pool should be worth at least an hour of Category I Credit.

Euphemisms are learned next. The statement on the brochure of "recently finished, spanking new" hotel means that not all the elevators work and the service personnel have not yet learned their jobs and that no one can be expected to speak English. Another hour of Category I Credit.

The curriculum is carefully laid out. It is studded with such expressions as: opening reception, gratuities and tips covered, free time, and spouses program. The accoutrements of learning are carefully recorded also, such as tennis, skeet shooting and golf available (greens fees not covered).

The faculty lists make heady reading. The same names turn up repeatedly so that you get the idea you are dealing with the academic jet set or the new medical beautiful people. You see some names on these lists so often that you wonder when they possibly can have time to do their research, their writing, their teaching of their own schools' students, let alone occasionally see a sick patient.

Arubascam was uncovered when a returning participant inadvertently leaked some information to a colleague who in turn inadvertently leaked it to a friend of his who was an investigator for the Internal Revenue Service. The remark that provided the leak seemed innocent enough on the surface. It was only, "I had a marvelous time, but I still didn't know what a normal platelet count was when I came home."

Harvey N. Mandell, M.D.

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The William W. Backus Hospital
Norwich, CT

Sick Physician Reporting Law

At the June 1980 meeting of the CSMS Council, it was voted that the reporting requirement of the "Sick Physician Law" again be promulgated to the Society's membership. Pursuant to this Council directive, we reprint here Circular Letter #1-72, sent to physicians by the State Department of Health on December 14, 1977:

Dear Fellow Physician:

As many of you are aware, the 1976 session of the General Assembly passed legislation updating the statutes which license physicians in Connecticut. An important part of this legislation related to the conditions and circumstances under which physicians must notify the Connecticut Medical Examining Board if they are aware that another physician might be practicing poor medicine. The statute states specifically under Section 20-13d(a) "The Connecticut State Medical Society or any county society, physician or hospital *shall* (emphasis added) . . . file a complaint when he, she, or it has information which appears to show that a physician is or may be unable to practice medicine with reasonable skill or safety. . . ." The Connecticut Medical Examining Board has developed procedures to review and investigate all complaints.

We are fortunate to have in Connecticut a medical community which adheres to the highest professional standards. However, we all, upon occasion, might come in contact with physicians who, for a variety of reasons, are not practicing medicine with "reasonable skill or safety." It is incumbent upon us, as fellow physicians, to identify these individuals and notify the Connecticut Medical Examining Board so that the physician in question can be helped and our profession and the public can be protected.

Sincerely,

Douglas S. Lloyd, M.D.
Commissioner

Multiple Sclerosis Simulating Pheochromocytoma

CHARLES A. GUNDERSEN, M.D.

ABSTRACT—A patient is reported who presented with systemic hypertension and signs and symptoms of catecholamine excess, during acute exacerbations of multiple sclerosis.

Although the clinical picture suggested the presence of a pheochromocytoma, this was not confirmed by laboratory and radiographic studies.

Evidence is presented to support the hypothesis, that the clinical syndrome was due to the underlying demyelinating process. This may have disrupted inhibitory neuronal pathways, resulting in unopposed discharge from the medullary vasomotor center and enhanced sympathoadrenal activity.

Introduction

Systemic hypertension has been observed in a variety of neurologic disorders that are capable of altering the activity of the medullary vasomotor center.

This case report describes a patient who presented with severe hypertension, and other clinical manifestations of pheochromocytoma, associated with an acute exacerbation of multiple sclerosis.

Case Report

A 26-year-old white woman was admitted to the Hartford Hospital on June 12, 1972, with an eight-day history of blurred vision, difficulty in swallowing, grand mal seizures, shortness of breath, abdominal pain, and bloody diarrhea.

Physical examination revealed a blood pressure of 120 mm Hg systolic and 80 mm Hg diastolic, a pulse rate of 92 per minute, and a respiratory rate of 24 per minute. The abdomen was diffusely tender and moderately distended with absent bowel sounds. On neurological examination, the left pupil was smaller than the right. There was pronounced nystagmus in all directions of gaze and some impairment of left lateral gaze. The right corneal reflex was depressed, speech was nasal in quality, and the soft palate did not contract. Finger to nose performance was dysmetric on the left side.

During her hospital course (6/12/72 - 8/23/72), she developed respiratory failure necessitating tracheostomy and a toxic megacolon, secondary to ulcerative colitis, requiring a total colectomy. Hypertension was not detected at any time during this hospitalization. By the time of discharge, the neurologic abnormalities had completely cleared, and a provisional diagnosis of multiple sclerosis was made.

On September 12, 1972, she was readmitted with complaints of severe generalized headache, flushing, diaphoresis, palpitations, dysarthria, difficulty swallowing, nasal regurgitation, and a choking sensation.

Physical examination revealed a blood pressure of 188/120 mm Hg, apical heart rate of 120 per minute, and a respiratory rate of 22 per minute with a chaotic breathing pattern. The left pupil was miotic. There was bilateral horizontal nystagmus present with a left conjugate gaze palsy and several fresh hemorrhages in the right fundus. The voice was nasal in quality, and the soft palate did not contract.

A complete blood count (CBC), erythrocyte sedimentation rate (ESR), anti-nuclear antibody (ANA) titre, fasting blood sugar, blood urea nitrogen, serum creatinine, serum electrolytes, arterial blood gases, and urinalysis were all normal.

The chest x-ray was normal but the electrocardiogram showed diffuse ST and T wave changes without evidence of left ventricular hypertrophy.

On the basis of these data, the suspected clinical diagnoses included multiple sclerosis or brain stem tumor to explain the neurologic picture, and pheochromocytoma or renal artery stenosis to account for her hypertension.

During the first ten days of hospitalization, daily blood pressures of 170/120 - 200/140 mm Hg were recorded with intermittent brief periods of normotension. She had persistent tachycardia without fever or signs of congestive heart failure. She continued to complain of headache, blurred vision, difficulty swallowing, and dyspnea.

Rapid sequence intravenous pyelography and bilateral renal and left adrenal arteriography were normal. Plasma renin activity was 19 nannograms per milliliter per hour (normal levels 0.75 - 2.75). Twenty-four hour urine determinations for vanillyl mandelic acid (VMA), metanephrines, and catecholamines were 11 milligrams (normal level <8), 2.5 milligrams (normal level <0.9), and 277 micrograms (normal level <200) respectively.

Roentgenograms of the skull were normal. The electroencephalogram was diffusely abnormal. A lumbar puncture with examination of the cerebrospinal fluid revealed a normal pressure, a protein concentration of 78 milligrams (normal 15 - 60) per 100 milliliters with 10 per cent gamma globulin, normal sugar and no cells.

From the 8th to the 15th hospital day, the patient's hypertension responded poorly to 200 milligrams of hydralazine and 100 milli-

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grams of hydrochlorthiazide per day. On the 15th day, these medications were discontinued and therapy was initiated with 40 milligrams of propranolol and 20 milligrams of dibenzyline orally per 24 hours. By the next day, she was normotensive and her tachycardia had resolved.

By the 20th day of hospitalization, all neurologic symptoms and signs had disappeared and she continued to be normotensive. All anti-hypertensive medications were discontinued and for the remainder of the hospitalization she maintained a normal blood pressure.

At the time of discharge, on the 25th hospital day (10/24/72), the 24-hour urinary VMA, metanephrines, and catecholamines were 2 milligrams, 0.7 milligrams, and 74 micrograms respectively. A provocative test with 25 micrograms of histamine intravenously failed to raise the blood pressure above a base-line of 102/68 mm Hg.

On December 4, 1972, the patient was admitted for the third time following a grand mal seizure. During this 9 day hospitalization, she was normotensive and had no signs or symptoms of bulbar involvement.

The 24-hour urine determinations for VMA, metanephrines, and catecholamines were all normal.

Although it was felt this patient almost certainly had multiple sclerosis, the presence of an intracranial neoplasm was still considered a possibility. Therefore, a carotid and vertebral arteriogram and pneumoencephalogram were performed, which were both negative.

On July 23, 1973, she experienced the acute onset of diplopia, associated with a right lateral rectus palsy, both of which resolved completely over a 13 day period.

On December 5, 1973, she developed a numbness of the left upper lip, tremor of the left hand, and weakness of the left leg. Physical examination revealed hyperesthesia of the left upper lip, bilateral horizontal nystagmus, incoordination and intention tremor of the left hand, absent left abdominal reflex, sustained left ankle clonus, and hyperactive reflexes throughout; left greater than right.

On January 30, 1974, she was admitted for the fourth time with a 3 day history of sweats, chills, generalized headache, palpitations, difficulty in swallowing, dizziness, and ataxia.

The physical examination revealed a blood pressure of 165/120 mm Hg with a pulse rate of 100 per minute without fever or signs and symptoms of congestive heart failure. Her affect was euphoric. There was bilateral temporal pallor of the discs and arteriolar spasm without hemorrhages or exudates. Coarse horizontal nystagmus was present on left lateral gaze with fine horizontal nystagmus on right lateral gaze. Speech was nasal in quality and palatal contraction was depressed. Reflexes were symmetrically hyperactive and no pathologic reflexes were elicited. There was an intention tremor involving the left hand, and she walked with a wide-based ataxic gait.

Complete blood count, blood urea nitrogen, serum creatinine, serum electrolytes, arterial blood gases, ESR, ANA titre, and urinalysis were all normal. Plasma renin activity was 7.2 nannograms per milliliter per hour (normal levels 0.75 - 2.75). Unfortunately, due to a collection error, urinary VMA, metanephrines, and catecholamines were not obtained.

During the first 5 days of her hospitalization, the blood pressure was in the range of 140/94 - 180/120 mm Hg with pulse rate of 96 - 128 per minute. On the 6th day, therapy was initiated with 40 milligrams of propranolol and 20 milligrams of dibenzyline daily by mouth, and within 24 hours she became normotensive, and her tachycardia and symptoms of headache, sweats, and palpitations resolved. Over the next few days, her neurologic signs and symptoms cleared, and she was discharged on the 14th hospital day.

From February 12, 1974 until the present time, she has remained normotensive without anti-hypertensive therapy. However, she has had several exacerbations of her neurologic disease.

In May, 1974, she had an episode of unilateral optic neuritis, characterized by acute loss of visual acuity and a lateral visual field defect in the right eye which resolved over an eight day interval. During the subsequent 2 year period, 1974 - 1976, she had three separate episodes of acute radiculitis manifested by pain and hypesthesia involving the T8 - T10, T5 - 6, and C5T1 dermatomes respectively, all of which resolved completely over a 5-7 day period. Since 1976, she has been asymptomatic but continues to manifest bilaterial horizontal nystágmus and left sided hyperreflexia.

The clinical course of neurologic lesions disseminated in time and place with exacerbations and remissions, and the exclusion of other etiologies resulted in a final diagnosis of multiple sclerosis.

Discussion

The primary central pressor areas have been shown to be located in the dorsomedial reticular substance of the medulla and floor of the fourth ventricle.[1-4] The intrinsic tonic discharge of these centers exerts its effect on the heart and peripheral vasculature via sympatho-adrenal pathways. Under experimental conditions, this tonic discharge can be augmented by direct physical or electrical stimulation, resulting in systemic hypertension and increased catecholamine production.[5] Under physiologic conditions, this tonic discharge is modulated by impulses originating in pressor areas located in the posterior hypothalamus and depressor areas located in the anterior hypothalamus.[6] In addition, impulses originating in the aortic and carotid sinus nerve receptors also modulate the tonic medullary discharge. These impulses are initiated by pulsatile expansion of the arterial walls, are transmitted via the glossopharyngeal and vagal nerve trunks, and terminate in the dorsal nucleus of the vagus and depressor areas of the medulla, which are situated in the dorsolateral and ventromedial substance. From these centers, inhibitory impulses are transmitted to the pressor areas in the medulla, dampening their tonic discharge.

Experimental section of the aortic and carotid sinus nerves in animals results in sustained hypertension.[7] Disruption of these nerves in humans by procaine block, has the same effect.[8]

Interference with these normal interactions, by disease, may produce systemic hypertension by augmenting the discharge from the medullary pressor centers. Clinically, this is seen under two pathologic conditions.

First, any condition that results in a rapid increase in intracranial pressure such as intracerebral hemorrhage, brain tumor, brain abscess, meningitis, encephalitis, and pseudotumor cerebri.[9-13] Cushing in 1903, was the first investigator to report the association of hypertension with increased intracranial pressure.[11] His explanation, which is still generally accepted, attributes the hypertension to a disturbance in the intracranial circulation, resulting in medullary ischemia and stimulation of the vasomotor center. On occasion, the clinical picture suggests the presence of a pheochromocytoma because of symptoms and laboratory evidence of catecholamine excess.[11,12]

Second, neurogenic hypertension has been reported in association with a variety of polyneuritic disorders, such as poliomyelitis, porphyria, and Guillain Barré syndrome.

Hypertension occurs in 33 - 70 percent of cases of poliomyelitis, particularly those with evidence of brain stem involvement and signs of respiratory insufficiency.[14-19] The hypertension is present despite adequate oxygenation and maintenance of a normal acid-base balance. It bears no relationship to the presence or absence of renal insufficiency.

Baker et al performed histologic studies of the brain stem in 80 cases of bulbar polio.[20] They showed a significant correlation between pathologic changes and the presence of hypertension. All cases associated with hypertension showed damage to the large reticular cells in the ventromedial reticular area of the medulla (vasodilator area). These findings were confirmed by Kemp who found ganglionic cell degeneration in the same anatomic area and suggested that the cause of the degeneration was probably the result of direct attack by the polio virus itself.[18]

Hypertension and tachycardia are common findings in the polyneuritic form of idiopathic porphyria. Kezdi reported a case in which hypertension was present only when clinical evidence of involvement of the ninth and tenth nerves was demonstrated.[6] He postulated that the hypertension was due to involvement of the sinoaortic nerves, either peripherally or at their termination in the ninth and tenth nuclei, causing disruption of their inhibitory effect on the medullary vasomotor center. Baker and Watson reported a case in which hypertension was associated with pathologic changes in the dorsal vagal nucleus and the reticular formation, supporting the hypothesis of Kezdi.[21]

Hypertension is also frequently seen in patients with the Guillain Barré syndrome. Haymaker and Kernahan reported significant hypertension in 11 of their series of 50 fatal cases.[22] McDowell and Plum observed hypertension in all 3 of their patients.[19] Each of these 14 patients had evidence of bulbar involvement with respiratory insufficiency and cranial nerve deficits. Mitchell and Meilman reported the case of a young woman who developed hypertension during the course of her illness, which was associated with clinical evidence of hyperactivity of the sympathetic nervous system, and elevated urinary VMA and catecholamines.[23] Lichtenfeld found hypertension in 17 of their 28 cases, all of whom, had clinical evidence of excessive sympathetic activity.[24]

The case of multiple sclerosis presented in this communication demonstrates many of the same clinical features that characterized the patients with poliomyelitis, porphyria, and Guillain Barré syndrome. She had definite evidence of bulbar involvement with evidence of cranial nerve deficit. In addition, she had significant hypertension with clinical and laboratory evidence of catecholamine excess, raising the clinical suspicion of pheochromocytoma. The bulbar involvement and hypertension manifested a close temporal relationship, exacerbating and remitting sequentially. Other possible causes of hypertension such as pheochromocytoma, renal artery stenosis, adrenal adenoma, and intracranial neoplasm, were investigated and excluded by renal, adrenal, and cerebral arteriography and pneumoencephalography; all of which were normal. The hypertension was present despite adequate oxygenation, normal acid-base balance, and normal intracerebral pressure, and was brought under control only by specific blockade of the alpha and beta adrenergic receptors.

It is postulated, therefore, that this woman's hypertension and syndrome of catecholamine excess were due to her underlying demyelinating process. This process interrupted the inhibitory pathways modulating the tonic discharge of the medullary vasomotor centers. This interruption might have occurred anywhere along the peripheral course of the ninth and tenth nerves, in the region of the nuclei, or in the depressor areas of the reticular formation. The net effect would be an excessive, unopposed discharge from the vasomotor center with enhanced sympathoadrenal activity and catecholamine secretion.

The same mechanism is probably operative in patients with other polyneuritic syndromes who manifest hypertension in association with bulbar neurologic deficits, and suggests that the treatment of choice for the hypertension is specific blockade of alpha and beta adrenergic receptors.

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Ectopic Ossification in the Abdominal Wall

KENNETH L. COHEN, M.D. AND KAREN A. MARLIN, P.A.-C

Ectopic ossification in an abdominal surgical scar is a rare variant of traumatic myositis ossificans. The radiographic findings are impressive and diagnostic.

Case Report

A 44-year-old black male with a history of chronic alcohol abuse and pancreatitis presented to the West Haven Veteran's Administration Hospital Emergency Room complaining of "discomfort" in a scar on his abdomen, especially upon bending over. The patient had undergone an exploratory laparotomy in 1972 because of a stab wound. He had noted an asymptomatic mass in the surgical scar in 1974 but had not sought medical attention for this problem. He denied any abnormal gastrointestinal symptoms.

Physical examination revealed a well-healed midline abdominal incision which extended from the xiphoid process to six centimeters below the umbilicus. At each end was a rock-hard mass, about two centimeters in diameter, in the superficial subcutaneous tissue. The rest of the scar was very firm but nontender. The exam was otherwise unremarkable.

Figure 1 is a lateral x-ray of the abdomen.

Comment

Soft tissue *calcification*, the amorphous precipitation of calcium salts, is a common phenomenon. Arterial calcification is a regular concomitant of aging; calcium deposits in the supraspinatous tendon produce a painfully frequent syndrome; and the necrosis of any soft tissue is often followed by calcification. In addition, a variety of systemic illnesses associated with hypercalcemia (eg hyperparathyroidism, hypervitaminosis D) or hyperphosphatemia (eg chronic renal failure, hypoparathyroidism) may lead to excessive calcium deposition in soft tissues.

Soft tissue *ossification*, formation of ectopic bone, is, by comparison, an uncommon phenomenon. It has been divided into three subtypes: a) myositis ossificans progressiva, b) neurogenic myositis, and c) traumatic or heterotopic myositis ossificans.[1] Myositis ossificans progressiva is a rare autosomal dominant disorder in which ossification occurs in the fibrous tissues of the muscle planes, resulting in sheets of bone which

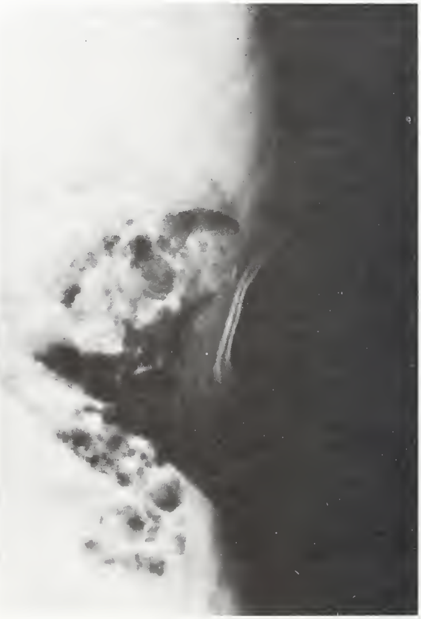

Figure 1
Ectopic ossification in the abdominal wall.

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severely limit mobility. Characteristic skeletal deformities, consisting of a short metacarpal of the thumb and a short metatarsal of the great toe, are present at birth. The abnormal calcium deposition begins in early childhood with discrete episodes of bone formation often triggered by minor trauma. Diphosphonate therapy may inhibit the ossification.

Myositis ossificans occurs in patients with spinal cord lesions; between ⅓ and ½ of paraplegics have bony deposits in the paralyzed part. The ossification occurs in muscles, tendons, and ligaments, particularly around large joints. Occasionally the bone formation may be massive enough to immobilize the joint.

Traumatic myositis ossificans may occur after extensive soft tissue injury, although minor trauma can also trigger this process. Certain occupations have been associated with specific locations for the ectopic bone formation such as the adductor longus muscle ("rider's bone"), the brachialis muscle ("fencer's bone"), and the soleus muscle ("dancer's bone"). Following an injury there is the sequential appearance of a soft tissue mass, irregular central calcification, and a centrifugal pattern of bone maturation resulting in mature lamellar bone, occasionally with marrow elements. The ectopic bone may regress with time.

Ectopic ossification in abdominal incisions is a rare subtype of traumatic myositis ossificans.[2 3] The typical patient is a mildly overweight male who has had a midline abdominal incision extending to the xiphoid cartilage. None of the reported cases have had any wound complications before the ossification occurred, and no patient had any metabolic disorder. The condition usually appears several months following surgery and may present as an asymptomatic mass or as a painful swelling in the incision. The cause of the ectopic ossification is unknown; proposed hypotheses have included the seeding of perichondrial cells from the xiphoid, and excessive suture line tension in the obese patient. In any case, treatment is limited to the symptomatic patient and consists of surgical removal of the ectopic bone. Recurrence is unusual.

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Simultaneous Parathyroid and Pharyngeal Tumors with Normal PTH and NcAMP

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ABSTRACT—Epidermoid carcinomas of the head and neck are capable of producing parathyroid hormone or parathyroid hormone-like substances and thereby cause hypercalcemia. A patient had simultaneously an epidermoid carcinoma of the pharynx and hypercalcemia, with normal serum levels of parathyroid hormone (PTH) and urine excretion of nephrogenous cyclic adenosine monophosphate (NcAMP). The hypercalcemia persisted despite successful radiotherapy of the tumor, and a large parathyroid adenoma was resected. In patients with epidermoid tumors of the head and neck, normal levels of PTH and NcAMP do not exclude the presence of primary hyperparathyroidism.

Hypercalcemia occurring in a patient with carcinoma is not an unusual occurrence. The etiology of the elevated calcium may be secondary to (1) skeletal metastasis (2) tumor secretion of prostaglandins,[1,2] osteoclast-activating factors, or PTH or PTH-like substances,[3,4] (3) primary hyperparathyroidism, or (4) associated disorders such as sarcoidosis, adrenal insufficiency, Vitamin D excess, Paget's disease of bone, thiazide diuretics, multiple myeloma, milk alkali syndrome, or renal or thyroid disorders.

Determining the cause of hypercalcemia can be difficult. A variety of laboratory tests are sometimes helpful in finding the cause. Recently the measurement of levels of PTH and NcAMP have been suggested as more specific tests of parathyroid function. Herewith is reported a patient who was found to have both a parathyroid adenoma and an epidermoid carcinoma of the pharynx, with symptomatic hypercalcemia and normal PTH and NcAMP levels. Such a patient with head and neck carcinoma might have been expected to

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have tumoral production of a PTH-like substance as the cause of hypercalcemia.

Case Presentation

A 72-year-old white woman (K.W.) developed a sore throat and consulted an Ear, Nose and Throat Specialist. A tumor was observed in the right peritonsillar area and a biopsy revealed a Grade II epidermoid carcinoma. A serum calcium of 13.4 mg/dl was found. She reported symptoms of polyuria, constipation, nausea, eight pound weight loss, lethargy, and decreased memory. She was taking no medications and the intake of calcium in her diet was estimated to be less than 800 mg in a 24 hour period. She was active at home.

Repeat calcium levels were 12.3, 13.1, 11.9, and 12.5 mg/dl. Other laboratory studies included a serum chloride of 108 meg/L, phosphate 2.3 mg/dl, creatinine 1.1 mg/dl, serum urea nitrogen 9 mg/dl, total protein 6.3 gm/dl, albumin 3.6 gm/dl, thyroxine 6.8 ug/dl. The calculated chloride/phosphate ratio was 47. Urine calcium excretion was 63 mg/24 hours. PTH level was 170 pg/ml and 162 pg/ml on repeat determination with a simultaneous serum calcium of 12.2 and 12.1 mg/dl respectively (performed by Metpath Clinical Laboratory, Teterboro, New Jersey using radioimmunoassay of the carboxyl terminal of PTH) indicating "non-parathyroid hypercalcemia". 24-hour urine NcAMP was 3.39 nanomols per 100 ml glomerular filtrate (performed by Dr. Arthur Broadus, Yale University School of Medicine, New Haven, Connecticut; normal up to 4.3 nanomols per 100 ml glomerular filtrate). Serum protein electrophoresis, bone marrow aspiration and bone biopsy, intravenous pyelogram, bone scan using technetium, metastatic bone series, ultrasound of the neck, and radiographs of the neck, skull, and hands were normal.

Radiotherapy was given for a total of 7 weeks (7000 rads), and the tumor diminished in size to approximately 80% as observed originally. Hypercalcemia continued (serum calcium 12.3, 11.9 mg/dl). Surgical exploration of the neck was performed and a 6 x 3 x 3 mm parathyroid adenoma was resected. Her post-operative course was uneventful except for transient hypocalcemia of 7.2 mg/dl which required no therapy. The serum calcium was normal one month and six months after the operation.

Comments

The occurrence of hypercalcemia in a patient with a carcinoma suggests the possibility of a humoral factor causing the hypercalcemia. Other possibilities exist however, and Table I lists the various causes of hypercalcemia associated with a neoplasm.

Table I

CAUSES OF HYPERCALCEMIA ASSOCIATED WITH NEOPLASM

1. Metastatic disease to the skeletal system
2. Primary hyperparathyroidism
3. Ectopic PTH or PTH-like substance
4. Tumor secretion of prostaglandins
5. Osteoclast-activating factors (OAF)
6. Vitamin D (or its metabolites) (3)
7. Non-Vitamin D Sterols (4)
8. Other causes of hypercalcemia (sarcoidosis, Addison's disease, diuretics, thyroid disorders)

The history helps to exclude ingestion of excess Vitamin D, milk and alkali, and thiazide diuretics. A significant weight loss and anorexia is very suggestive of a neoplastic process and the acute onset of hypercalcemia is more indicative of ectopic secretion of PTH by a tumor than primary hyperparathyroidism. The detection of elevated calcium levels prior to the presence of detectable tumor is highly suggestive of primary hyperparathyroidism. Renal calculi and nephrocalcinosis are unusual with metastatic carcinoma or the paraneoplastic secretion of PTH. The presence of anemia is more suggestive of a neoplasm than primary hyperthyroidism. If the calcium levels do not fall following treatment of a tumor then one obviously looks for another cause for the hypercalcemia other than the tumor.

The chloride phosphate ratio is useful in the diagnosis of primary hyperparathyroidism and was 47 in this patient. Palmer, et al[5] reported that 96% of patients with primary hyperparathyroidism had a chloride-phosphate ratio greater than 33 and this same ratio was less than 30 in patients with hypercalcemia from other causes. Parathyroid hormone causes an increased renal excretion of phosphate and bicarbonate with a subsequent reciprocal rise in the serum chloride resulting in hyperchloremic acidosis.[6] The use of serum phosphate measurement alone as an indicator in hyperparathyroidism is often not reliable.[7] The chloride-phosphate ratio has been reported to be helpful in differentiating between the ectopic secretion of PTH (pseudohyperparathyroidism) and primary hyperparathyroidism.[8]

The availability of PTH immunoassay in the 1960s[9] provided what was thought to be a specific and sensitive definitive test for the diagnosis of disorders of parathyroid metabolism. Because of technical difficulties and the existence of different forms of PTH (pre PTH, pro PTH, hexapeptide, parathyroid secreting protein) the measurement of PTH by commercial laboratories is often unreliable.[9-11] One reportedly accurate method to measure PTH is to use radioimmunoassay of the carboxyl terminal region of the parathyroid hormone and comparing these results with simultaneous values of serum calcium as described by Arnaud, et al.[12]

This method is useful not only in differentiating metastatic disease to bone and hyperparathyroidism, but also in differentiating ectopic hyperparathyroidism from primary hyperparathyroidism, the latter reportedly having higher levels of immunoreactive PTH than in the former.[13] Other methods of measuring the level of PTH may involve antibodies binding to the NH_2-terminal portion of PTH and may be less reliable.[13] Laboratories may try to measure the whole PTH polypeptide or the N-terminal fraction of PTH or the C-terminal fraction of PTH. In this patient, the PTH was normal on two separate measurements by carboxyl terminal assay. It is our opinion that the medical literature gives some very impressive results of reliability of the PTH determination that conflict with the reliability of commercial laboratories available to the practitioner.

There has been recent interest in the measurement of nephrogenous cyclic adenosine monophosphate (NcAMP) and the total cyclic AMP excretion (UcAMP) in diagnosing hypercalcemic states. Parathyroid hormone activates an adenyl cyclase enzyme resulting in increased levels of cyclic 3′ 5′ AMP in the renal proximal tubule and subsequently also in the excreted urine. Approximately 40 to 50% of the total urinary cyclic AMP is produced by the action of PTH in the kidney.[14] It is questionable whether measurement of UcAMP is helpful in diagnosis of hypercalcemic states.[15,16]

Using the UcAMP, serum calcium, and parathyroid hormone determination, Shaw et al,[17] reported that 54 to 56 patients with primary hyperparathyroidism (10 HPT) had inappropriate high UcAMP levels when compared to the serum calcium levels and that this measurement was useful in separating patients with PTH and non-PTH mediated hypercalcemia. Broadus, et al recently suggested that NcAMP was elevated in 91% of the 57 patients he studied with 1°HPT.[18] The measurement of NcAMP has been confirmed by others to be reliable in separating hyperparathyroid conditions from other causes of hypercalcemia.[19] NcAMP does not seem to differentiate 1°HPT from ectopic PTH syndromes.[19] This patient had normal excretion of NcAMP (3.39 nanomoles/100 ml gf).

While attempting to identify the cause of the hypercalcemia in our patient, attention was directed towards the possibility of ectopic production of PTH from the epidermoid carcinoma of the pharynx (pseudohyperparathyroidism). Albright has been credited as being the first to suggest that a malignant neoplasm might secrete PTH.[20] Later studies confirmed that hyperparathyroidism could be present in patients with a malignancy and normal parathyroid glands.[21-25] The phrase "pseudohyperparathyroidism" was applied by Lafferty[25] and Snedecor and Baker[26] and specifically meant the presence of hypercalcemia and hypophosphatemia in a patient with a malignancy and neither metastasis to the skeletal system nor 1°HPT. Many different neoplasms have been reported to result in pseudohyperparathyroidism. The most well-known are malignant tumors of the lung, kidney, uterus, vulva, adrenal, cervix, and reticulum cell sarcomas and other lymphomas. The measurement of NcAMP in such patients has been used as a test of pseudohyperparathyroidism in such patients.[19]

Pseudohyperparathyroidism in head and neck tumors has also been described.[24,27,28] Tumoral PTH secretion might have been suspected in our patient. However, because she had persistent elevation of serum calcium following successful shrinking of the tumor with radiotherapy, and because she had an elevated chloride/phosphate ratio and because other causes of hypercalcemia were ruled out, 1° HPT was strongly suspected despite normal PTH and NcAMP levels. Surgical exploration revealed a large parathyroid adenoma.

We were able to find very few reports of the presence of both 1°HPT and a malignancy capable of producing PTH in the same patient,[19] and could find no reports of this combination with normal PTH and NcAMP levels. In patients with hypercalcemia and epidermoid carcinoma of the head and neck, the presence of normal levels of PTH and NcAMP does not exclude the presence of primary hyperparathyroidism.

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Abdominal Lymph Node Evaluation Applications of Computerized Tomography

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ABSTRACT—Computerized tomography can be utilized as the primary imaging tool in evaluation of retroperitoneal lymph nodes. In a patient with an equivocal study, or in whom a strong clinical suspicion exists in spite of a negative C.T., lymphangiography should be performed. If the initial C.T. is unequivocally positive, lymphangiography is not necessary. For follow-up of nodal disease, C.T. and possibly ultrasound, are the procedures of choice.

Introduction

Staging of lymphoma, testicular carcinoma and certain other diseases requires evaluation of lymph nodes. Prior to computerized tomography (C.T.) and modern gray scale ultrasound, lymphangiography, and occasionally nuclear medicine, were the nonoperative staging tools available. Each of these diagnostic tools has advantages and disadvantages which will be discussed.

Lymphangiography

Prior to 1950, lymph node evaluation was possible only in an operative manner. In the early 1950's, the lymphatics were cannulated and contrast was injected. For the next quarter century, bipedal lymphangiography was the undisputed standard for lymph node evaluation in the abdomen.[1] However, lymphangiography is an invasive study requiring a high degree of skill to perform. In addition, it is associated with allergic reactions and is contraindicated in lung disease.

Bipedal lymphangiography visualizes the inguinal, iliac and peri-aortic nodes to L2 (cisterna chyli). Nodes which are not opacified cannot be evaluated in lymphography. Therefore, nodal disease above the cisterna chyli, in the internal iliacs, or draining from the testicles, will be missed by lymphography. The ability to visualize texture enables abnormalities to be perceived prior to nodal enlargement, a distinct advantage of lymphangiography.

Much of the criticism of lymphography results from its failure to diagnose nodal disease in patients with testicular carcinoma. This failure occurs because the glandular drainage of the testes is via a unit of six to eight trunks that ascend in the spermatic cord and follow testicular blood vessels. These lymphatic trunks empty into the preaortic nodes adjacent to the renal bed. Hence, these nodes would not ordinarily visualize with bipedal lymphography.

Nuclear Medicine

Radionuclides can be prepared in a colloidal form and utilized for radionuclide lymphangiography. Localization of colloidal radioisotopes such as gold-198, technitium-99, and indium-111 is via phagocytosis by reticuloendothelial cells within the lymph nodes. The specific group of nodes to be imaged determines the specific site of injection. For pelvic and abdominal nodes, the cutaneous tissues of the foot are utilized. Poor spatial resolution has limited the usefulness of this technique within the abdomen.[2]

Gallium-67 citrate is the radionuclide which has been most successful in lymph node evaluation, especially with tumors arising in the liver, lung, or lymphatic system. Injected intravenously this radionuclide localizes in both neoplastic and inflammatory areas. Advantages include simplicity, localization in extra-abdominal sites such as the mediastinum and axilla, and reproducibility making it useful in evaluating recurrent disease. Disadvantages occur in abdominal scanning because significant activity within the colon, liver, and spleen hamper visualization of nodes adjacent to these structures.

C.T. and Ultrasound

Delineation of early nodal disease in the abdomen with C.T. and ultrasound relies on visualization of the great vessels. The abundant fat in the retroperitoneum surrounds the aorta and inferior vena cava (IVC) allowing imaging of the great vessels (Figure 1). As lymph node enlargement begins, the vascular angles between the aorta and IVC are "silhouetted out" so that the margins of the great vessels can no longer be

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imaged. With continued nodal enlargement, the great vessels are displaced forward, and lymph node masses can be readily visualized (Figure 2).

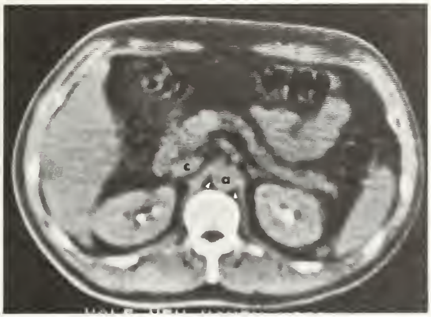

Figure 1

A normal C.T. scan through upper abdomen clearly defines the aorta (a) and inferior vena cava (c). Note the normal "fat angles" (white arrowheads) around the aorta.

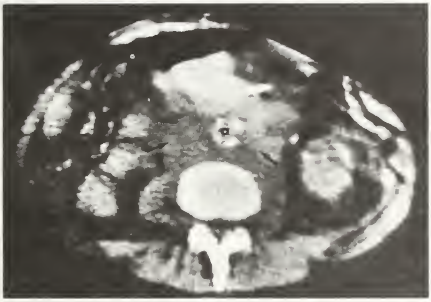

Figure 2

A lymphomatous mass (outlined by arrows) has destroyed the normal fat angles and has lifted the calcified aorta (a) forward—"floating aorta sign". (Courtesy of C. Jaffe, M.D., Yale-New Haven Hospital)

C.T.

Unlike lymphangiography, the detection of nodal disease with C.T. is based only on lymph node enlargement.[3] A false negative result may occur with internal architectural distortion without nodal enlargement. Also, C.T. lacks the ability to distinguish lymphoma from metastatic disease, a distinction which can usually be made with bipedal lymphangiography.

C.T. does have certain distinct advantages over lymphangiography. Organs of importance for staging, such as the spleen, liver, and pancreas can be imaged. In addition, if present, hydronephrosis can be detected by contrast enhanced C.T. Nodes not seen by lymphangiography because they are too high in the abdomen or obstructed will be readily visualized. This noninvasive test is easily performed, repeatable, and requires no patient preparation.

Ultrasound

Ultrasound, like C.T., is useful in nodal evaluation only after nodal enlargement has occurred. The main disadvantages of ultrasound remain the degradation of the image because of abdominal gas, residual barium, and fat. These limitations hamper the evaluation of pelvic and lower abdominal nodes.

Ultrasound is useful in the upper abdomen where gas is less of a problem. Unlike lymphangiography, it can evaluate the liver, spleen, pancreas, kidneys, and high abdominal nodes (Figure 3). It is easily repeatable and requires no patient preparation.[4,5] Advantages over C.T. occur when little fat is present, or paraaortic metallic clips are in abundance, preventing adequate C.T. evaluation. In addition, serial exams in young patients, in whom radiation exposure would be a real consideration, favors ultrasound.

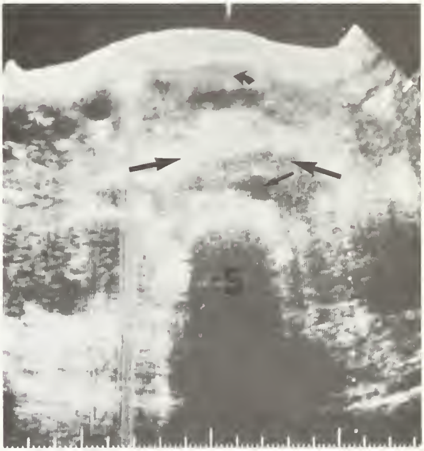

Figure 3

A transverse sonogram through the upper abdomen demonstrates anterior displacement of the pancreas (curved arrows) by a large retroperitoneal mass (large straight arrow). The aorta (small straight arrow) is in normal position (s = spine).

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Percutaneous Nephrostomy—Interventional Radiology

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Percutaneous placement of nephrostomy drainage tubes has been regarded as a temporizing measure prior to corrective urologic surgery. More recently, nonsurgical techniques using either multiside hole or Foley balloon catheters have been developed. The following cases demonstrate indications for percutaneous nephrostomy in two patients whose medical condition precluded surgery.

Case History

Case I

Five years prior to admission, a 55 year old female was diagnosed as having breast cancer and had a modified radical mastectomy. Three years prior to admission, recurrent chest wall metastases and supraclavicular nodes were noted. The only therapy she permitted was an experimental immune chemotherapy. On this admission, she presented with anuria of twenty-four hours duration. Emergency retrograde pyelography revealed massive right hydronephrosis and blockage at the left uretero pelvic junction with notching of the left ureter consistent with periureteral tumor involvement confirmed by subsequent lymphangiogram.

The right kidney either became non-functional or the indwelling right ureteral catheter blocked, and subsequent renal nuclide scan and ultrasound showed poorly functioning kidneys with bilateral hydronephrosis. The patient remained anuric with medical therapy and a left percutaneous nephrostomy was performed with relief of obstruction and continued diuresis thereafter. (Figures 1 and 2) Three months after a course of radiotherapy, tumor regression permitted removal of the percutaneously placed nephrostomy tube.

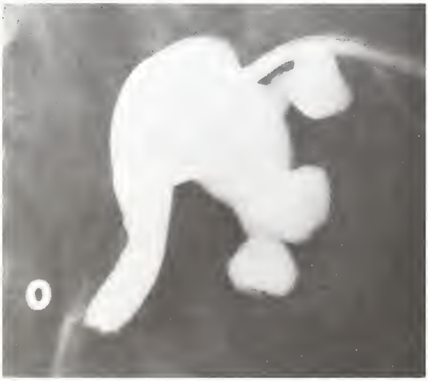

Figure 1

Antegrade pyelogram revealing hydronephrosis due to obstructing retroperitoneal metastases. (Case 1)

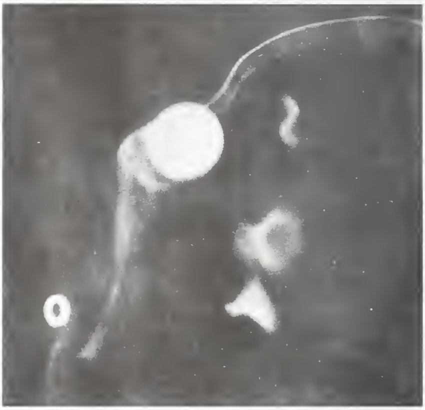

Figure 2

Post drainage film showing percutaneously placed Foley catheter functioning and in place. (Case 1)

Case II

A 63-year-old paraplegic male with an ileal loop bladder was admitted with several days of fever, malaise, shaking chills, and back pain. A diagnosis of septicemia secondary to urinary tract infection was made and the patient placed on antibiotics. Symptoms persisted despite therapy. Renal ultrasound showed a hydronephrotic right kidney with multiple internal echoes consistent with pyonephrosis. The intravenous urogram demonstrated a radiopaque calculus in the right ureter at the L4-5 level with proximal obstruction. Because of the patient's other serious medical problems and generally poor status, a percutaneous permanent type silastic Foley balloon catheter was placed. All symptoms and signs of infection quickly responded to nephrostomy drainage and the patient subsequently had an uncomplicated surgical removal of the stone.

Discussion

The first case is an example of temporary urinary diversion for supravesical obstruction to permit palliative and/or curative radiotherapy. The second case demonstrates use of this procedure in a patient with supravesical obstruction complicated by severe infection. Other indications for percutaneous nephrostomy are 1) for relief of obstruction to allow closure of a fistula, 2) for palliation of symptoms of incurable malignancy, 3) to allow time for resolution of postoperative edema or passage of a calculus, 4) for drug installation to dissolve calculi or treat obstructing urothelial tumors, and 5) in obstructed patients with infection and/or azotemia in whom surgery would be hazardous.[1]

Percutaneous nephrostomy allows anatomical delineation of the site and nature of urinary obstruction

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and following prolonged drainage permits assessment of the remaining renal function. Barbaric and Thompson discuss its use in the management of renal transplants to determine whether obstruction or rejection is the major contributor to post operative renal failure.[2]

Literature review of 516 percutaneous nephrostomies showed successful results in over 90%, with major complications limited to 4% and minor complications to 15%.[1] The major contraindication is severe bleeding diathesis. Techniques are reviewed by Stables, Ginsberg, and Johnson.[1] This radiologic procedure should be recognized as an important diagnostic, therapeutic, and palliative tool in the management of patients with urinary obstruction who might otherwise be at extreme risk or unsalvageable by standard surgical techniques.

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Pulmonary Paragonimiasis in a Recent Refugee from Southeast Asia

WILLIAM E. HART, M.D.

The following patient with proven pulmonary paragonimiasis is described in order to alert physicians in the state who may encounter refugees from Southeast Asia in their practices.

In July 1979 this 11¾-year-old male native of Laos was referred to Saint Francis Hospital and Medical Center from another medical facility where a chest x-ray, apparently taken as part of a screening process for immigrants from S.E. Asia, was found to be abnormal. He had resided in several different refugee camps in Thailand for the previous three years. Six months earlier he had experienced an episode of moderately severe hemoptysis for which he received both injected and ingested medications; this was followed by improvement although an intermittent slightly productive cough persisted. It is believed that a chest X-ray taken just prior to departure for the USA was abnormal. Three months ago he developed pain and swelling in the right ankle which did not interfere with normal activity. Denied were fever, lymphadenopathy, hematuria, other joint involvement, anorexia, weight loss. Past medical history suggests that he had been in relatively good health; four siblings are said to have died, at ages 6 months to 3 years, from unknown causes, but perhaps related to the war. The mother (39) and the father (42) are well and live in the Hartford county. One brother (16) is alive and well. The patient was enrolled in school for three weeks in the spring. The day before admission, he had received diphtheria-tetanus toxoid, trivalent oral polio vaccine and combined measles-mumps-rubella vaccine.

Temperature 98°F., Pulse 90, Respirations 20, BP 96/70, Weight 24 Kg. Apart from small size he appeared normal. Dental caries was noted. There were small shotty cervical nodes and a larger right axillary node. Over the right medial malleolar area was a warm tender swelling.

Hgb. 13.8 Gms/dL., Hct. 40%, reticulocyte count 3%. WBC 5,500/cumm. (33 segmented - 7 band - 39 lymph - 9 mono - 11 eosinophil). ESR 62 mm/hour. Urinalysis normal. Usual blood chemical determinations normal. Acid-fast stained smear of sputum was negative for AFB. Multiple ova were seen in specimens of stool, many of A lumbricoides, few of hookworm, occasional of P. westermani and rarely of T. trichiura. Ova of P. westermani were also identified in the sputum. (Figure 1). First (1 TU) and intermediate

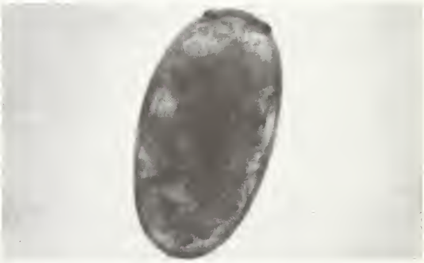

Figure 1

Ovum of Paragonimus westermani in sputum specimen from the patient

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(5 TU) tuberculin skin tests were negative as were skin tests for C. albicans and SK/SD. Chest X-ray suggested consolidation involving the right upper lobe and perhaps some paratracheal adenopathy; X-ray of the right ankle suggested considerable soft tissue swelling, but no involvement of bone; X-rays of skull were normal. EKG was normal, and results of pulmonary function tests were within normal limits.

Pending the arrival of bithionol with its protocol from CDC, the patient received a course of mebendazole for the three intestinal parasites. Then bithionol therapy, 500 gm. b.i.d. every other day for a total of 15 dose days, was begun. The protocol calls for three negative sputum examinations three months following cessation of therapy and chemical monitoring for hepatic and renal toxicity at the start and cessation of therapy. The patient's clinical condition improved and chest X-ray became normal.

On 9 September he was readmitted for treatment of the ankle lesion which continued to bother him; there was concern that the lesion represented a cutaneous manifestation of the parasite. Surgical excision was successfully performed with good healing. The histologic diagnosis was inflammatory tissue with necrosis; there was no granulomatous disease.

Publications from the U.S. Department of Health, Education and Welfare[1] and from the Center for Disease Control[2] as well as from other sources[3] have described in detail the medical issues raised by the current immigration from Southeast Asia. Among the diseases cited are tuberculosis, diphtheria,[4] malaria and hepatitis[5] as well as several parasitic diseases of the gastrointestinal tract. To date these publications have not mentioned paragonimiasis but a recent report of a case from a neighboring state suggests that physicians in Connecticut be made aware of its existence.[6]

Paragonimus westermani, the Oriental lung fluke, is a small macro-organism measuring 12 x 5 x 5 mm. and capable of causing extensive disease in the lungs and other tissues. Its distribution involves three continents, Asia, Africa and South America. Ova, either expectorated or passed in the stool, which find their way into fresh water and undergo incubation become larvae which, after infecting an indigenous snail and undergoing transformation, ultimately infect the second intermediate host, a fresh water crab or crayfish. Ingestion of the latter by a human completes the life cycle. The usual pathology is an abscess or granulomatous cyst-like structures in the lung or elsewhere. The clinical picture is commonly one of chronic, poorly resolving pulmonary disease in which hemoptysis may be a major symptom. The frequency of this as a presentation has led to the use of the term "endemic hemoptysis" in the Orient and elsewhere. Diagnosis is based on clinical findings and the identification of characteristic ova in the sputum or feces. An intradermal skin test has been developed for use when sputum is sparse and the diagnosis is strongly suspected especially in unusual sites, e.g., the central nervous system.[7 8] The Oriental custom of eating pickled but uncooked fish insures the preservation of the complete life cycle. There is a broad spectrum of severity, and mortality is low. Bithionol as an effective drug for therapy was introduced in Japan in 1961 and has been in world-wide use.[9] The main element of prophylaxis is adequate cooking of the intermediate host, fresh water crabs and crayfish.

In the instance of the current group of refugees, the disease, while causing a personal health problem for the infected individual, does not represent a public health issue apart from the confusion that may result when the presenting signs and symptomatology are considered to represent tuberculosis which was the initial concern in the case described. The use of BCG vaccine in Southeast Asia as well as the temporary anergy to tuberculin produced by administration of attenuated live measles vaccine may add to the confusion and uncertainty. The patient presented received a battery of vaccines including measles as part of his initial experience with an American health care facility.

Knowledge that pulmonary paragonimiasis has been observed locally should cause physicians to consider its presence in immigrants from Southeast Asia with acute or chronic pulmonary disease, especially when hemoptysis is present.

Addendum Since the original submission of this report, a second patient, an eight-year-old native of Cambodia, was found to have the same disease, positive identification being based on the presence of the characteristic ova of P. westermani in the sputum and the stool. The clinical course was similar to that of the first patient described and the child was discharged following a hospitalization of six days.

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Pulmonary Function in Runners Before and After a 20 Kilometer Road Race

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AND JACOB LOKE, M.D.

ABSTRACT—To evaluate the effects of long distance running on lung function, we measured the forced vital capacity (FVC) and maximum expiratory flow rates in thirty-four runners before and immediately after completion of a 20 kilometer race. Measurements of pulmonary function were obtained with a flow-volume device and an X-Y recorder which displayed a maximum expiratory flow-volume curve. There was a significant decrease in the mean post-race FVC (4.2%), and the "faster" runners had a greater decrement (7.7%) than the "slower" runners (2.9%) ($p < 0.05$). For all runners there was no change in the mean post-race flow rates. As airways obstruction did not develop in runners, the decrease in FVC may reflect fatigue of the respiratory muscles.

Introduction

Long distance running involves multiple physiological factors, of which the cardiovascular, pulmonary, and musculoskeletal systems are most important. Although previous studies have evaluated various aspects of breathing during exercise[1 2] or with increased airway resistance,[3] the direct effects of long distance running on the respiratory system have not been extensively investigated.[4] Gordon and colleagues[5] reported a 17% decrease in the forced vital capacity (FVC) of the lungs in 20 runners before and after the 1923 Boston Marathon (40.3 kilometers). Hug[6 7] observed a similar reduction of 16-18% in the post-race FVC during 2 marathon studies in Switzerland in 1927 and 1928. However, to our knowledge, there are no data of pre- and post-race maximum expiratory flow rates of the lung in long distance runners. To determine if there was a change in lung flow rates following a long distance race, we measured forced expiratory volume in one second (FEV_1), $FEV_1/FVC\%$, peak expiratory flow (PF), and maximum expiratory flow rate at 50% of FVC (MEF50) in thirty-four runners before and immediately after completion of a 20.0 kilometer race.

Methods

The New Haven Road Race (NHRR) was held on September 4, 1978, and consisted of a single loop measuring 20.0 kilometers. Pulmonary function testing was performed in a building located within 0.05 kilometer from both the start and the finish of the race. All participants in the breathing tests were contacted prior to the day of the race and informed consent was obtained. On the morning of the race day each runner had his height and weight measured and completed a questionnaire on respiratory symptoms and running experience.

Pulmonary function was measured with a pneumotachygraph integrated flow-volume device[8] connected to a Brush 500 High Performance X-Y recorder (Gould Inc., Cleveland, Ohio) which displayed a maximum expiratory flow-volume (MEFV) curve (Figure 1). Four MEFV curves were measured in each runner before and immediately after completion (with-

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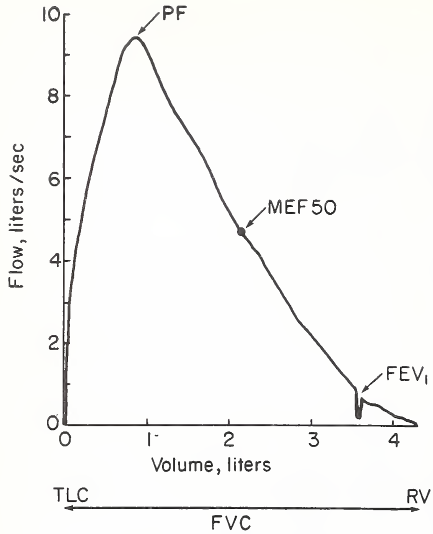

Figure 1
Maximum expiratory flow-volume curve of a normal subject. TLC-total lung capacity; RV- residual volume. (for definition see text.)

in ten minutes) of the 20 kilometer race. Values for FEV$_1$, FVC, PF and MEF50 were obtained from the MEFV curves. The mean of the two best pre- and post-race measurements for FEV$_1$, FVC, PF, and MEF50 were used to represent pulmonary function. These results were compared to predicted normal values of lung function established by Higgins and Keller.[9] Pre- and post-race data were analyzed using the paired t-test.

In addition, three runners who had a reduced pre-race FEV$_1$/FVC (< 70%) were further studied in the Pulmonary Function Laboratory. Maximal expiratory flow rates before and after inhalation of isoproterenol were determined on a Collins maxi modular lung analyzer.[10] Exercise performance was evaluated by progressive graded exercise[11] to exhaustion on a cycle ergometer (Monark). Values for oxygen consumption ($\dot{V}O_2$) were obtained from a Beckman metabolic measurement cart with an OM-11 oxygen analyzer. Predicted values for maximum oxygen uptake ($\dot{V}O_2$max) were taken from Astrand.[12] An electrocardiogram was used to monitor cardiac frequency. MEFV curves were recorded before as well as five, ten, and fifteen minutes after exercise to evaluate for the presence of exercise-induced asthma.[13]

Results

Thirty-four runners participated in the study. There were thirty-two males and two females with a mean age of 32.4 years (range, 20-66 years), and their mean running distance was 52.7 miles/week. Two runners gave a history of asthma; neither was taking medication nor experienced any wheezing during or after exercise. Nine runners were former smokers, and no subjects had respiratory symptoms of cough or sputum production.

Runners were arbitrarily divided into Group 1 [< 6 minutes/mile (1.6 kilometers)] and Group 2 [> 6 minutes/mile (1.6 kilometers)] in order to evaluate whether there was any difference in post-race lung function in "faster" runners as compared to "slower" runners (Table 1). The mean running time for the "faster" and "slower" runners to complete the 20 kilometer race was 70 minutes and 85 minutes, respectively.

All subjects had a normal pre-race FVC. There was a significant decrease in the mean FVC from 5.04 ±

Table 1

PRE- AND POST-RACE PULMONARY FUNCTION IN GROUP 1 [< 6 MINUTES/MILE (1.6 KILOMETERS)], GROUP 2 [> 6 MINUTES/MILE (1.6 KILOMETERS)], AND ALL RUNNERS IN THE 1978 NEW HAVEN 20 KILOMETER ROAD RACE

	Age (yrs)	*FVC (liters)*		*FEV$_1$ (liters)*		*MEF50 (liters/sec)*		*PF (liters/sec)*	
		pre	*post*	*pre*	*post*	*pre*	*post*	*pre*	*post*
Group 1 (n = 11)									
MEAN	28.0	4.93	4.55	4.14	4.00	5.31	5.02	9.10	9.25
S.E.M.	1.6	0.11	0.10	1.10	0.09	0.17	0.17	0.20	0.20
P		< 0.05		NS		NS		NS	
Group 2 (n = 23)									
MEAN	33.9	5.07	4.92	3.95	4.09	4.98	5.08	9.41	9.47
S.E.M.	2.1	0.11	0.11	0.09	0.10	0.25	0.25	0.33	0.33
P		<0.025		<0.025		NS		NS	
All Runners (n = 34)									
MEAN	32.4	5.04	4.82	4.01	4.08	5.08	5.05	9.32	9.42
S.E.M.	1.5	0.10	0.10	0.09	0.09	0.22	0.22	0.30	0.29
P		<0.005		NS		NS		NS	

NS = not significant

0.10 liters (mean ± SEM) before the race to 4.82 ± 0.10 liters after the race ($p < 0.005$).

The mean pre-race FEV_1 was 4.01 ± 0.09 liters. Of the two runners who had a reduced pre-race FEV_1, one had a history of asthma and the other was shown to have mild airways obstruction. For all runners there was no change in mean post-race FEV_1 (4.08 ± 0.09 liters). However, subjects in Group 2 showed a significant increase in FEV_1 after the race ($p < 0.05$).

Three runners, all from Group 2, had pre-race FEV_1/FVC ratios of less than 70%.

The mean pre-race PF was 9.32 ± 0.30 liters/sec, and the mean post-race PF was 9.42 ± 0.29 liters/sec (p = NS). There was no significant difference between the mean pre-race MEF50 (5.08 ± 0.22 liters/sec) and the mean post-race MEF50 (5.05 ± 0.22 liters/sec).

Subsequent testing of the three runners who had abnormal pre-race FEV_1/FVC ratios (58.9%, 59.6%, 66.4%) revealed that two subjects had reversible obstructive airways disease. Both individuals had at least 15% improvement in FEV_1 and MEF50 after inhalation of isoproterenol. The third subject had normal pulmonary function tests. There was no decrease in FEV_1 or MEF50 in the three runners after progressive exercise to fatigue on the cycle ergometer. Evaluation of exercise performance showed that the two subjects with airways obstruction had a maximum oxygen uptake of 44.3 and 40.5 ml/kg/min at a work load of 1,200 and 1,350 kpm/min, respectively.

Discussion

Airways obstruction did not develop in thirty-four runners after the 20 kilometer NHRR. In fact, the post-race FEV_1 showed a slight, but significant, increase in subjects of Group 2. The reason for this is unclear, however, it may be related to the release of endogenous catecholamines during exercise which leads to bronchodilatation.[14]

Since airways obstruction did not contribute to the decrease in post-race FVC, the role of respiratory muscle function must be considered. Ouellet, Pok, and Beckland[15] showed that fatiguing levels of ventilation (greater than 55% of the maximal voluntary ventilation[16]) are achieved at high levels of exercise. Although Roussos and Macklem[3] demonstrated that high inspiratory loads can be tolerated indefinitely if the transdiaphragmatic pressure (Pdi) is 40% or less of maximal Pdi, they state that if the energy consumption of the breathing muscles is excessive, respiratory muscle fatigue could develop and lead to exercise limitation. Certainly during long distance running the respiratory muscles can be involved in high intensity work which may result in fatigue. As these muscles are used to perform a FVC maneuver, a decrease in the strength of the ventilatory muscles[17] could explain the reduction in the FVC.

Muscle function during an endurance form of physical activity is dependent on several factors such as skeletal muscle respiratory enzymes,[18] muscle fuel metabolism,[19] and circulation.[20] Saltin and Karlsson[21] compared the rates of glycogen depletion from muscle biopsies of the quadriceps femoris that occurred at different intensities and duration of bicycle exercise; they found a greater depletion of muscle glycogen associated with a shorter duration of exercise performance at high intensity work as opposed to exercise of low intensity. Muscle glycogen appeared to be the limiting factor since exhaustion coincided with extremely low muscle glycogen levels. We showed in our study that the "faster" runners had a greater decrease in the FVC compared to the "slower" runners; this may be due to a higher intensity of running, leading to a relatively greater depletion of glycogen in the "faster" runners. However, the reduction in the mean post-race FVC was considerably less than that observed by Gordon et al[5] and Hug[6 7] in marathon runners. A possible explanation is that our runners experienced less glycogen depletion because of the shorter running distance and less intense work.

In addition, two runners were subsequently evaluated in the pulmonary function laboratory and were shown to have reversible airways obstruction. One had a previous history of asthma. Exercise-induced bronchoconstriction did not develop in either subject after the 20 kilometer race or after exhaustive exercise in the laboratory. Both subjects achieved their predicted maximal oxygen uptake and have completed a marathon race (42.2 kilometers) despite their mild airways obstruction.

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When it had been shown by the researches of Pasteur that the septic properties of the atmosphere depended not on the oxygen, or any gaseous constituent, but on minute organisms suspended in it, which owed their energy to their vitality, it occurred to me that decomposition in the injured part might be avoided without excluding the air, by applying as a dressing some material capable of destroying the life of the floating particles. Upon this principle I have based a practice of which I will now attempt to give a short account.

The material which I have employed is carbolic or phenic acid, a volatile organic compound, which appears to exercise a peculiarly destructive influence upon low forms of life, and hence is the most powerful antiseptic with which we are at present acquainted.

—Joseph Lister, M.D., 1867, in his publication in the *British Medical Journal,* introducing the concept of antisepsis.

The Management of Multiple Myeloma

SHARON LUIKART, M.D. AND RICHARD B. WEININGER, M.D.

Multiple myeloma occurs in 2 to 4 per 100,000 Americans with approximately equal sex distribution. The age of onset is generally in the fifth decade, though it ranges from early childhood to old age.

Diagnosis

The diagnosis is often suspected clinically, particularly in the setting of elderly patients with bone pain, renal disease, anemia or unexplained infections. Certain laboratory features are required and include: increased numbers of abnormal, atypical or immature plasma cells in the bone marrow or histologic proof of plasmacytoma, the presence of a monoclonal protein in the serum or urine and lytic bone lesions and/or osteopenia. Plasma cells may be seen in the peripheral blood, particularly late in the disease, and a small number of patients (1-2%) with bone disease and plasmacytosis will not have a monoclonal serum or urine protein ("non-secretors"). These diagnostic criteria are summarized in Table I.

Table I

DIAGNOSIS OF MYELOMA

I. Plasmacytosis of the Bone Marrow
   A. Presence of "sheets", clusters, or "syncytiae" of abnormal cells
   B. Increased numbers of plasma cells by differential count, which are often cytologically abnormal
II. Monoclonal serum protein in two-thirds of patients, monoclonal urine protein in two-thirds, and both in fifty percent
   A. "Background" immunoglobulins are depressed in ninety percent of patients
   B. Only one or two percent of patients will have no monoclonal protein ("nonsecretor")
III. Evidence of Bone Destruction
   A. "Punched-out" lytic lesions of the axial skeleton
   B. Diffuse osteopenia
   C. Hypercalcemia
   D. Bone pain, tenderness and pathologic fractures

Because myeloma cells generally secrete a measurable immunoglobulin product, multiple myeloma has been studied as a model of tumor cell kinetics. Hobbs[1] introduced a constant exponential growth concept that suggested a pre-clinical phase of a decade or more. Salmon,[2] studying *in vitro* cellular rates of immunoglobulin synthesis, proposed a Gompertzian model of growth which provides for a much briefer preclinical period of 1-3 years. This model predicts a rapid tumor growth rate in the pre-clinical phase and a much slower growth rate by the time the tumor is clinically evident. A further extension of the Salmon approach is the calculation of total body myeloma cell number or "tumor burden", based on *in vitro* immunoglobulin synthesis and *in vitro* cell number. Durie and Salmon[29] have attempted to correlate "tumor burden" with clinical stage. Their staging system is consonant with the statements of Waldenstrom,[30] Snapper,[31] and others: namely, that patients with severe bone disease, hypercalcemia, and large monoclonal "spikes" have more advanced disease and generally do less well. Unfortunately, the value of using the tumor burden concept has yet to be proven in clinical trials or practice. It fails to adequately account for the influence of renal dysfunction and pretreatment performance status, thought by several authors to be important prognostic indicators.[3,4,5]

After the clinician makes the diagnosis of myeloma, and considers the stage, the question then remains as to how best to treat the disease and manage its complications. The complications of multiple myeloma are protean and span all of internal medicine.

Disease Complications

Renal failure may occur as a presenting feature of myeloma, more commonly with disease progression, or as an iatrogenic event. Acute renal failure as an initial manifestation of the disease should be treated aggressively, as many patients will regain function on dialysis if their disease is controlled.[6] Renal failure occurring during disease progression is usually an ominous

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finding, indicating that protein production and hypercalcemia are beyond control, or that renal amyloidosis has supervened. In either case, the outlook is poor. Iatrogenic, and therefore preventable causes of renal failure are those which follow intravenous urography[7] or severe hyperuricemia. Intravenous pyelograms should be avoided in all myeloma patients, and especially in those who secrete Bence-Jones protein. If the study cannot be avoided, then the patient must be well hydrated before, during, and after the procedure. Similar care must be taken in managing hyperuricemia—though myeloma patients rarely produce the amount of uric acid seen in leukemics, they are capable of producing enough to destroy kidneys which have borderline function.

Hypercalcemia occurs in about one-third of patients at the time of diagnosis. Symptoms include anorexia, nausea, vomiting, polyuria, polydipsia, confusion or coma. Urgent treatment is necessary to prevent renal impairment. These patients are frequently dehydrated, so that saline hydration, which promotes the renal excretion of calcium, is always the initial treatment. Diuresis with furosemide may also be beneficial. Prednisone, perhaps related to its *in vitro* ability to inhibit osteoclast activating factor,[8] is particularly effective in treating hypercalcemia in myeloma patients. In patients resistant to these measures, an infusion of "low dose" mithramycin, 15-25 μg/kg, is usually effective and may be repeated several times before encountering the hematologic, renal and hepatic toxicities associated with this drug.

These therapies require 12-48 hours to significantly lower the serum calcium. When a more urgent situation exists, dialysis, calcitonin with phosphate,[9] or hyperventilation may be tried.

Skeletal lesions, which almost always accompany hypercalcemia, produce pain and fractures and are major problems. Skeletal radiographs are superior to radioisotope bone imaging for evaluating the extent of disease,[10] though rib lesions may be better visualized on the bone scan.[28] Standard therapy for bone pain and/or impending fracture is radiotherapy in relatively low doses (1000-2500 rads). This is frequently effective in controlling bone pain, though the prophylactic use of intramedullary rods in large lytic lesions of long bones may be of benefit when impending fracture or structural instability are present. Bone lesions rarely heal with chemo- or radiotherapy, so that other means of improving bone structure on a long term basis have been sought. Ambulation prevents long term release of calcium from bone and resultant disuse osteopenia. Sodium fluoride and calcium have been used as supplements to chemotherapy. Kyle and Jowsey reported an increase in trabecular and cortical thickness,[11] though the degree of clinical benefit[12] is marginal. Recently, dichloromethylene diphosphonate, an inhibitor of bone resorption, has been shown to decrease urinary excretion of calcium in myeloma patients. The long-term effect on bone resorption is unknown.[13]

Extradural extension of myeloma lesions may compress the spinal cord, particularly in the lower thoracic and upper lumbar regions. Irradiation is frequently effective therapy, but if neurologic deficits progress, surgical decompression may be necessary.[14] As in all malignancies, the combination of back pain and neurological findings should prompt emergency investigation and treatment.

Bacterial infections are frequent in myeloma due to depression of "background" immunoglobulins as well as granulocytopenia from either the myeloma or its treatment. The organisms involved most frequently are *S. pneumoniae, H. flu,* and the gram negative enterics. As in other compromised hosts, they must be managed by careful attention to culture results coupled with appropriate antibiosis. Though the long-term use of gamma globulin infusions has been shown to be of no value,[15] its potential benefit during the acute infectious episode is unknown.

Certain clinical complications are secondary to the monoclonal proteins themselves rather than the malignant process in general. Hyperviscosity may be associated with IgG or IgA myeloma, although it is more common with macroglobulinemia. Symptoms include decreased visual acuity, neurologic abnormalities, bleeding, and congestive heart failure.[16,17,18] Most patients are symptomatic at a relative serum viscosity of 4 to 8. Plasmapheresis is the treatment of choice, though it is often difficult to perform effective plasmaphereses if the protein is IgG or IgA because of the relatively small size of these proteins compared to IgM. The size differences dictate that IgG or IgA will be distributed within the entire extracellular volume (15-20 liters) and will thus require prolonged and frequent plasmaphereses.

Hemorrhage may be a manifestation of increased viscosity, though protein related coagulopathies may exist independent of hyperviscosity. The most common of these is a coating of the platelet membrane by immunoglobulin, leading to thrombocytopathic bleeding when the platelet count may be normal. The immunoglobulin may also interfere with coagulation factors, either by "nonspecific" adherence, or more rarely because the monoclonal immunoglobulin is an antibody to one of the coagulation factors.[19] Finally, vascular purpura may occur as an early manifestation of amyloid infiltration of small vessels.

Therapy

The disease complications described above are manageable by a variety of ancillary measures, and are indirectly treated by reducing the plasma cell number with chemotherapy. Malphalan has long been the standard chemotherapy for multiple myeloma. There are similar response rates and survival with intermittent and daily dose schedules,[20] and cyclophosphamide appears to be equally effective.[21] Prednisone is added to melphalan or cyclophosphamide as initial therapy in most clinical trials, though the survival advantage of the combination is based on a single group trial.[22] Prednisone alone does not affect survival in multiple myeloma.[23] Corticosteroids produce a fall in serum proteins and a decrease in proteinuria perhaps due to increased catabolism, but the most important effect is to reduce serum calcium. Thus, corticosteroids should be a part of the treatment regimen in hypercalcemic myeloma patients, though they have also become part of virtually all drug combinations in use today.

Combination chemotherapy has not shown dramatic success. The best results have been reported with the M-2 protocol, a combination of three alkylating agents —alkeran, cytoxan, BCNU—as well as vincristine and prednisone.[24] The median survival in previously untreated patients was 48 months, but those studies are uncontrolled and patient selection criteria are poorly defined. Other studies have suggested that poor-risk patients (high tumor cell burden) may be the group to most benefit from multiple agents,[5] though the survival benefit appears to be small.

Response in myeloma is generally measured in terms of a decrease in serum and urine proteins, stabilization of lytic lesions, normalization of serum calcium, and correction of anemia and hypoalbuminemia if they are secondary to myeloma.[25] Patients who respond rapidly have a shorter median survival,[4] a clinical observation which correlates with the proliferative capacity of the tumor. Thus, because response rate, time to response, and survival often correlate poorly in myeloma, one is obliged to use overall survival as the ultimate gauge of therapeutic effectiveness.

The effect of the kind of therapy, and the duration of therapy have been examined for myeloma. The duration of therapy may be of critical concern because of the high incidence of acute leukemia in myeloma patients treated with alkylating agents (recently reported to be 17.4% at 50 months post-diagnosis[25]). In an attempt to reduce the total dose of alkylating agent, it has been suggested that therapy be discontinued in responding patients after an arbitrary period of time. Alexanian reported similar survival times in 28 patients who were in remission after 12 months and discontinued therapy compared to patients receiving indefinite chemotherapy. In those that relapsed, 80% obtained a second remission.[26] These data are encouraging, and correlate with the authors' experience, though they require confirmation in a larger, better controlled trial.

In patients who fail melphalan and prednisone, as noted previously, some obtain a remission with other alkylating agents such as cytoxan or BCNU.[21] Adriamycin alone has shown a 20-30% response rate in melphalan-prednisone failures,[27] and the combination of adriamycin and BCNU has been reported to offer an overall response rate of 50%. Hexamethylmelanine has had variable early results, and trials are still ongoing. Similarly, hemi-body radiation has shown a reasonable response rate and almost universal pain relief in far advanced patients, though with a high complication rate. Because of those complications (pneumonitis, leucopenia), we have initiated a pilot study using lower doses at several week intervals rather than single large doses. Initial results are encouraging, but we need to accrue more patients before anything meaningful can be said. Finally, interferon is now being used in previously untreated myeloma patients. Early results indicate that its efficacy is somewhat less than melphalan's and that responses may vary dramatically depending upon the origin of the interferon. It is likely that the use of interferon in myeloma trials will soon be relegated to the therapy of relapsing patients.

Summary

With proper hydration, analgesia and general supportive measures in addition to chemotherapy, patients with multiple myeloma are living for longer periods after diagnosis. Most series report median survivals in the range of 22 to 30 months. Renal failure, recurrent infections and debilitation remain the most common causes of death. The treatment of the disease complications is at least as challenging as the underlying malignancy, though primary therapy for myeloma is far from satisfactory. There are numerous ongoing studies attempting to improve the outlook in this disease.

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The AMA and Number and Distribution of Physicians

HEW (now HHS) recently said medical schools are geared to bring the physician supply into balance with national needs in the Eighties. But the need for better distribution of the supply, geographically and functionally (with emphasis on primary care), would persist.

An AMA position paper said "the use of incentives, education, encouragement and exhortation (to improve distribution) is infinitely preferable to prescription of numbers, types, and location of physicians by legislation or regulation."

The AMA's commitment to voluntary approaches over the years:

- The Millis Report of 1966, issued by an AMA-appointed citizens' commission, stressed the need for "primary" physicians;
- The AMA in 1969 was instrumental in recognition of family medicine as a specialty;
- The AMA House of Delegates in 1973 recommended that 50 per cent of all medical graduates enter residency training in primary care specialties. The goal was soon exceeded.

The AMA helped boost the number of medical schools to the present 126 and has supported adequate federal funding of medical and allied-health education.

—AMA *Fact Sheet on Physicians*, May, 1980

Gynecologic Oncology: Cancer Update

(Second of Two Parts)

DANIEL KAPP, M.D. AND PETER E. SCHWARTZ, M.D.

Ovary

Ovarian cancer is the second most common cancer of the female reproductive organs, but has the highest mortality rate associated with cancers in the reproductive sites.[1] Unlike endometrial cancer which has an obvious early warning signal, abnormal bleeding, resulting in early diagnosis, or cervical cancer which can be diagnosed before clinical symptoms develop by the routine use of the PAP smear, ovarian cancer in early stages is not usually associated with obvious early warning signals, and there is no routine screening test which may be employed for finding early or localized ovarian cancer. In most large series approximately 60 to 70% of patients at presentation will be found to have disease spread outside of the pelvis, that is Stage III or Stage IV.[80] The current F.I.G.O. staging system for ovarian cancer is presented in Table III.

Table III

F.I.G.O. STAGING SYSTEM FOR CARCINOMA OF THE OVARY

Stage I	Growth limited to the ovaries.
Stage Ia	Growth limited to *one* ovary; no ascites (i) No tumor on the external surface; capsule intact (ii) Tumor present on the external surface and/or capsule ruptured
Stage Ib	Growth limited to *both* ovaries; no ascites (i) No tumor on the external surface; capsule intact (ii) Tumor present on the external surface and/or capsule(s) ruptured
Stage Ic	Tumor either Stage Ia or Stage Ib, but with ascites* present or positive peritoneal washings
Stage II	Growth involving one or both ovaries with pelvic extension.
Stage IIa	Extension and/or metastases to the uterus and/or tubes.
Stage IIb	Extension to other pelvic tissues.
Stage IIc	Tumor either Stage IIa or Stage IIb, but with ascites* present or positive peritoneal washings
Stage III	Growth involving one or both ovaries with intraperitoneal metastases outside the pelvis and/or positive retroperitoneal nodes. Tumor limited to the true pelvis with histologically proven malignant extension to small bowel or omentum.
Stage IV	Growth involving one or both ovaries with distant metastases. If pleural effusion is present there must be positive cytology to allot a case to Stage IV.

Special category. Unexplored cases which are thought to be ovarian carcinoma.

*Ascites is peritoneal effusion which in the opinion of the surgeon is pathological and/or clearly exceeds normal amounts.

The most important features in managing ovarian cancer are first, to carefully stage the patient surgically, then to remove all gross cancer whenever possible, and to provide appropriate adjuvant therapy based on the histologic appearance of the tumor, its stage, and the volume of residual cancer left behind at the initial surgery.[81] Although "debulking" with excision of as much tumor as possible has long been advocated, there exists little evidence to show that this results in improved survival unless all or nearly all of the gross tumor is excised.[82-85] To adequately stage ovarian cancer one must employ a surgical incision which will allow adequate evaluation, not only of the pelvis, but of the paraaortic lymph nodes, diaphragm, liver, omentum, and the large and small bowel. Use of a Pfannensteil incision compromises the ability to accurately stage the cancer, and can lead to inappropriate recommendations for adjuvant therapy postoperatively.[87] Studies from the National Cancer Institute have recommended routine laparoscopy in patients who appear to have had inadequate surgical incisions to determine the extent of disease spread in the upper abdomen.[87] Patients studied in this fashion and thought at prior laparotomy to have disease confined to the pelvis were determined to have metastases to the diaphragm and liver serosa at the time of laparoscopy prior to the initiation of chemotherapy. These findings are based on a limited number of patients. In more recent studies

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occult diaphragmatic or liver serosal metastasis were found less frequently at pretreatment laparoscopy in previously untreated recently surgically staged patients, reflecting perhaps more careful staging of these areas at the time of the initial surgery.[88-90]

Careful intraabdominal exploration at the time of the initial surgery is the key to proper staging of patients with ovarian cancer.[81] Following the careful intraabdominal exploration and determination of the spread pattern of the cancer, aggressive surgical technique is extremely important, as the patient with the best prognosis is the one with the least amount of cancer left behind at the initial surgery.[82-85] A minimum goal should be to remove gross tumor greater than one cm in diameter and preferably to remove all gross tumor.[84] Aggressive surgical technique must be followed by aggressive adjuvant therapy to achieve satisfactory survival rates.[82]

Patients with early stage ovarian, epithelial cancer, i.e., cancer confined to the ovaries or involving the pelvis, but nevertheless totally resectable, may benefit from either adjuvant radiation therapy to the whole abdomen and pelvis or cytotoxic chemotherapy.[3,91] Studies have strongly suggested that pelvic irradiation alone is not adequate therapy for managing early stage ovarian cancer and radiation fields should cover the entire peritoneal cavity including the diaphragm.[3,92,93] An attempt to increase the intensity of radiation administered to the upper abdomen by employing moving strip irradiation has become quite popular.[3,94] Recent data would suggest that this technique employed in patients with Stage I, Stage II, and asymptomatic Stage III cancer who have undergone a TAH-BSO and have no gross residual cancer have an extremely high survival rate, whereas patients with gross residual cancer treated in this fashion tend to do poorly.[3,95] Other investigators have attempted to increase the survival rates by boosting the diaphragm areas and retroperitoneal lymph node bearing areas, or alternatively, using gapped abdominal and pelvic fields treated sequentially after several hours delay.[96-98] Preliminary results of these experimental techniques have been good but more time is necessary to analyze them.

During the past decade single agent prospective randomized studies using cytotoxic chemotherapy have established that the alkylating agents including cyclophosphamide and melphalan, adriamycin, cis-diamminedichloroplatinum, and hexamethylmelamine are each active as single agents in the management of advanced ovarian cancer, and combinations of these agents appear to be more active.[99] A recently completed prospective randomized study at YNHH and its affiliated hospitals has demonstrated that the combinations of adriamycin and cyclophosphamide, and hexamethylmelamine and cyclophosphamide are equally active in managing advanced epithelial ovarian cancers and these combinations have a higher response rate than published results for single agents.[100] Adriamycin-cyclophosphamide is particularly active in poorly differentiated ovarian cancer. The combination of hexamethylmelamine, cyclophosphamide, methotrexate, and 5-fluorouracil (Hexa-CAF) is superior to melphalan in advanced ovarian cancer.[101] Adriamycin and cis-platinum in combination is reported to be more active than single agent alkylating therapy.[102, 103]

Preliminary data employing the combination of cyclophosphamide, hexamethylmelamine, adriamycin, and cis-platinum has yielded very high response rates.[104,105] However, combination therapy carries with it significant toxicity.[100,102] It is clear that more prospective randomized studies are necessary with attention being paid to the presence or absence of residual tumor and the grade of the tumor in advanced stages of disease.[100] In patients with minimal residual disease preliminary data from a prospective randomized study comparing melphalan to whole abdominal irradiation using the moving strip technique and with additional irradiation to the pelvis would suggest that there is no statistical significant difference in survival with these two approaches as adjuvant therapy.[91] In patients with bulk residual disease, radiation therapy is usually paliative and the emphasis is currently on the role of aggressive debulking surgery followed by aggressive, adjuvant, combination chemotherapy programs for epithelial ovarian cancer.[82]

Steroid receptor hormone research at YNHH has confirmed the presence of estrogen receptor protein in the cytosol of approximately 50% of epithelial ovarian cancers.[106] A preliminary trial of antiestrogens at YNHH in advanced and recurrent ovarian cancer has demonstrated stabilization of rapidly progressing cancer which has failed standard therapy.[107] New protocols are being developed at YNHH for advanced ovarian cancer which will include not only cytotoxic chemotherapy, but also anti-estrogen therapy. A protocol is also being developed for early stage ovarian cancer comparing external beam radiation to the whole abdomen and pelvis with combination cytotoxic chemotherapy.

In contrast to the rather slow progress being made in the management of the common epithelial cancers, the past decade has seen a dramatic increase in the survival of the rather rare non-eithelial cancers of the ovary employing combination chemotherapy consisting of vincristine, actinomycin-D, and cyclophosphamide (VAC). Preliminary data would suggest that early stage germ cell tumors such as the immature teratoma and the endodermal sinus tumor which had an extremely poor prognoses in the past may now be completely controlled using combination chemotherapy.[108] VAC chemotherapy has been demonstrated to be active in stromal tumors and preliminary data from YNHH supports VAC chemotherapy for mixed mesodermal tumors of the ovary.[109, 110]

Dysgerminomas, another type of rare germ cell tumor of the ovary, have been shown to be quite radiosensitive, similar to their male counterpart, the seminoma. Recent studies have revealed excellent survival rates, with the M.D. Anderson Hospital reporting 86% long-term survival among 36 patients treated, and Memorial Hospital reporting 91.7% (11 of 12 patients) of their previously untreated patients remaining free of disease from 2 to 38 years (median 6 years).[111,112] Excellent control has also been reported in patients presenting with advanced disease—by total hysterectomy and bilateral salpingo-oophorectomy followed by whole abdominal, pelvic, and adjunctive mediastinal irradiation.[113] In carefully selected patients desiring preservation of childbearing capacity, post-operative x-ray therapy has been withheld following unilateral oophorectomy for limited disease.[111] For all other patients with more advanced disease, TAH-BSO followed in most cases by whole abdominal and pelvic irradiation, with boost to involved pelvic masses or involved paraaortic nodes, is recommended. Prophylactic irradiation of the mediastinum and supraclavicular areas should be considered in patients with positive paraaortic nodes.[111] Experience at YNHH suggests the value of lymphangiography in postoperative patients for aiding determining radiation fields when intraoperative staging was incomplete.

Despite the demonstrated response of granulosa cell tumors to moderate radiation doses the role of post-operative irradiation in treatment of these tumors remains controversial.[114] Several recent studies have demonstrated improved survival in patients treated postoperatively to the whole abdomen and pelvis but the small number of patients in these nonrandomized series, and the tendency for late recurrences in granulosa cell tumors prevents definitive conclusions from being drawn.[110,115] Patients at YNHH with Stage Ib to III disease with minimal residual tumor after total abdominal hysterectomy and bilateral oophorectomy are treated with whole abdominal and pelvic irradiation in a manner similar to the treatment of epithelial tumors of the ovary.

Immunotherapy has been investigated in the management of ovarian cancer. There is evidence to suggest that non-specific immunostimulation using C. parvum or BCG may enchance response rates when given in combination with cytotoxic chemotherapy.[116,117] Much work remains to be done with these agents before they can be routinely employed in the management of advanced and recurrent ovarian cancer.

Vulva

The vulva is an area of skin that appears to have an increased tendency to develop preinvasive and invasive cancers. The premalignant changes may be indistinguishable from benign processes for which topical therapy may be appropriate. The clinician is strongly urged to biopsy any suspicious lesions in the vulva and to biopsy those lesions which appear to be benign in nature but fail to respond fairly promptly to topical therapy.

The management of intraepithelial neoplasias of the vulva has generally been wide local resection. There is a tendency for carcinoma-in-situ (CIS) of the vulva to be multi-focal, and it is advocated that the entire vulva be removed in the fashion of a skinning vulvectomy for treatment of CIS.[118] The site that the skin is removed from may be covered with a split thickness skin graft, providing the patient with soft, pliable tissue which may result in a more satisfactory sexual experience.

Invasive cancer of the vulva is managed surgically with radical vulvectomy and bilateral superficial inguinal and deep pelvic lymphadenectomies. It has recently been suggested that microinvasive cancer of the vulva not associated with lymphadenopathy may be treated if it is limited in size and depth of invasive with a wide local excision in carefully selected patients.[119] Others have advocated biopsying the superficial femoral lymph nodes to be certain that microscopic spread of disease is not present.[120] Such management requires very close follow-up of patients, and those patients in whom careful follow-up is not deemed possible should undergo radical surgery. The current TNM staging system for vulvar cancer is presented in Table IV.

Table IV

TNM CLASSIFICATION OF CARCINOMA OF THE VULVA

T Primary tumor	
T1	Tumor confined to the vulva—2 cm or less in largest diameter.
T2	Tumor confined to the vulva—more than 2 cm in diameter.
T3	Tumor of any size with adjacent spread to the uretha and/or vagina and/or perineum and/or anus.
T4	Tumor of any size infiltrating the bladder mucosa and/or the rectum mucosa or both, including the upper part of the urethra mucosa, and/or fixed to the bone.
N Regional lymph nodes	
NO	No nodes palpable.
N1	Nodes palpable in either groin, not enlarged, mobile (not clinically suspicious of neoplasm).
N2	Nodes palpable in either groin or both groins, enlarged, firm and mobile (clinically suspicious of neoplasm).
N3	Fixed or ulcerated nodes.
M Distant metastases	
MO	No clinical metastases
M1a	Palpable deep pelvic lymph nodes
M1b	Other distant metastases.

Prognostic factors of significance in vulvar cancer are the extent of the local disease, unifocal or multifocal disease, involvement of mucous membranes of the urethra, vagina, rectum, clitoral involvement, and spread to superficial inguinal and deep pelvic lymph nodes.[121] The number of regional lymph nodes involved is of prognostic significance in that those patients with four or more lymph nodes involved in the bilateral superficial and deep inguinal lymphadenectomy specimen tend to have a survival rate of less than 25 percent, whereas those patients with three or less nodes involved have a survival rate of over 60 percent.[122]

A unilateral superficial inguinal lymphadenectomy for patients with discrete unilateral lesions has been advocated at YNHH. If the lymphadenectomy specimen is free of metastatic cancer no further surgery is performed as the benefits derived from bilateral superficial inguinal and deep pelvic lymphadenectomies may be less than the mortality associated with this extensive operative technique when metastatic cancer is not present.[123] However, at YNHH bilateral superficial inguinal and deep pelvic lymphadenectomies are performed in those individuals with metastatic cancer found in the ipsilateral superficial inguinal lymphadenectomy specimen.

Definitive radiation therapy in vulvar cancer has not been widely employed in the United States although several European series employing high energy electrons or supervoltage irradiation in selected patients yielded results believed comparable to surgery.[124-126] It is clear that radiation may reduce the size of tumor in the vulvar area resulting in changing a non-resectable lesion into a resectable one.[127] However, insufficient experience in the United States is currently available for assessing the routine use of radiation therapy as an alternative to radical surgery in vulvar cancer. A recent preliminary study has suggested a role for prophylactic irradiation of clinically negative groin nodes subsequent to radical vulvectomy.[128] More work is needed in this area. Cytotoxic chemotherapy experience has been extremely limited in vulvar cancer and the results to date have been rather unrewarding.[129]

Melanoma has been reported to be the second most common malignancy involving the vulva and has an extremely poor prognosis when metastases are present in regional lymph nodes.[130] New approaches using high dose fractions of radiation therapy may have more to offer the patient.[131] It is unclear at this time whether the depth of invasion of the melanoma in early stage disease is of the same prognostic significance when the tumor arises in the vulva as when it arises in other areas of the body.[132] The treatment policy at YNHH is wide local excision for early stage melanoma of the vulva. Advanced melanoma requires aggressive approaches with radiation therapy and possible chemotherapy.

Vagina

Carcinoma of the vagina remains an infrequently occurring malignancy. It is most often a squamous cell cancer occurring in older-aged group women.[133] Adenocarcinomas are quite rare but have been reported in older aged women and are usually a papillary type.[134] Recently attention has been focused on diethylstilbestrol exposure in utero and its association with clear cell adenocarcinoma in the vagina of women in their second and third decades of life.[2] It is now well established that women exposed in utero to diethylstilbestrol (DES) and other hormones will have a very high likelihood of having benign changes in the shape of the cervix and the vagina. These changes have been classified as coxcomb and hooded cervices and have been associated with transverse vagina septa as well as the presence of columnar epithelium and gland formation in the vagina, i.e., adenosis.[135] In a very small group of women (between one in one thousand and one in ten thousand), exposed in utero to such hormones, clear cell adenocarcinoma has developed.[136] Usually the carcinoma is found in the vagina although a number of patients have had either involvement of the vagina and the cervix, or cervical involvement only with clear cell adenocarcinoma.

Attention has been focused on screening women exposed in utero to diethylstilbestrol to determine benign and malignant changes in this population. Careful inspection and palpation of the vagina and cervix, colposcopic assessment of the vagina and cervix, and iodine staining techniques appear to be very acceptable for determining the presence of any abnormalities.[137] Those changes suspicious for cancer should be biopsied. As benign changes occur at such a high frequency in women with DES exposure, it is probably in the patients' best interest to be followed by a physician experienced in the evaluation of DES exposed patients. Virtually all of the clear cell adenocarcinomas of the vagina have been confirmed at the time of the initial careful evaluation of patients looking for the source of abnormal bleeding or the presence of an occult malignancy when the patient presents for routine screening.[138]

There is a suggestion that an increased incidence of cervical and vaginal squamous intraepithelial neoplasia is associated with DES exposure in utero.[139] More recent data would suggest that some of the preliminary changes reported to be dysplastic actually represented immature squamous metaplasia, a benign change.[140] It would be wise to consult with pathologists experienced in DES associated changes before aggressive therapy is recommended for the management of preinvasive changes in vaginal and cervical epithelium in DES exposed patients.

Management of the clear cell cancers has most frequently been aggressive radical surgery which results in the need for vaginal reconstruction or alternatively, radiation therapy.[136] Local therapy has been employed in a very small group of patients. Such treatment must be selected specifically for those patients with minimal invasion and small lesions. Regional lymph nodes should be evaluated prior to employing local therapy only. Long-term follow-up is unavailable at this time, but local treatment may place patients at an unnecessary high risk for recurrence, the management of which has not been satisfactory.

At YNHH patients with clear cell adenocarcinomas of the vagina are treated with intracavitary and external beam radiation therapy, avoiding the need for vaginal reconstructive surgery. Early stage clear cell adenocarcinoma of the cervix has been treated with radical hysterectomy and bilateral deep pelvic lymphadenectomy, thereby preserving ovarian function. Ovarian function may be preserved in patients with vaginal clear cell carcinoma by performing an oophoropexy prior to initiation of external beam radiation. Lymph nodes may be sampled at the time of oophoropexy to determine appropriate radiation fields.

Squamous cell carcinomas of the vagina are treated at YNHH in a similar manner employing a combination of intracavitary radium and external beam irradiation to the draining lymph nodes.

Malignant melanoma of the vagina is a rare disease with a very poor prognosis.[130] A surgical approach has been stressed in the literature, but perhaps here, too, as well as in the melanoma of the vulva, high dose fraction irradiation may play a role.

Fallopian Tubes

Fallopian tube cancer occurs infrequently and clinically acts very much like an epithelial cancer of the ovary. When a malignancy involves both the fallopian tubes and the ovary, by convention, the cancer is considered to be ovarian in nature. Patients with fallopian tube carcinoma are managed at YNHH by excision of the tumor mass, TAH-BSO, followed by aggressive adjuvant therapy using protocols similar to those for ovarian cancer. Good results have been reported employing surgery and postoperative irradiation for early stage disease.[141]

Trophoblast Disease

The most significant advances in gestational trophoblast disease have been the introduction of effective cytotoxic chemotherapy and the development of the serum assay for beta human chorionic gonadotropin (HCG) using radioimmunoassay techniques.[5] This has allowed the clinician to follow a biologic marker to determine whether a patient has persistent trophoblast disease following the termination of a pregnancy and identify those patients who require chemotherapy. It also determines when a patient may safely discontinue chemotherapy for gestational or non-gestational metastatic trophoblast disease.

A practical classification for those patients at high risk for developing malignant sequelae has been developed and this classification has been used in determining effective management for patients with either non-metastatic or metastatic gestational trophoblast disease.[142] Patients with non-metastatic disease have persistent disease present in the uterus following evacuation of a hydatidiform mole. Less frequently this will be as a result of malignant sequelae following an abortion or term gestation. Persistent intrauterine disease may be treated with single-agent chemotherapy consisting of methotrexate or actinomycin-D and will permit retention of reproductive function.[142]

Patients with metastatic gestational trophoblast disease are divided into a low or good risk group and a high or poor risk group.[142] The low risk group consists of patients who develop malignant sequelae within four months following the termination of the last known pregnancy, have metastases to the vagina or to the lungs and have a 24-hour urine chorionic gonadotropin titer (UCG) less than 100,000 international units. The poor risk group consists of those patients whose last normal pregnancy was terminated more than four months prior to the diagnosis of metastatic gestational trophoblast disease and have metastases identified in the brain or liver or have a 24-hour UCG titer greater than 100,000 international units. Recent evidence suggests two additional groups of patients who may fit into the poor risk category, i.e., gestational trophoblastic disease occurring following termination of a term gestation and poor risk category patients treated with single-agent chemotherapy.[143,144]

The good risk group is readily treated with single-agent chemotherapy consisting of either methotrexate or actinomycin-D, whereas the poor risk group requires prompt institution of combination chemotherapy employing methotrexate, actinomycin-D and an alkylating agent.[142]

Alternative cytotoxic chemotherapy has been investigated in managing those patients with recurrent or persistent trophoblast disease following standard therapy. It would appear that poly-chemotherapy employing a seven drug regimen may be effective in those patients who have failed standard therapy.[145] There is preliminary evidence at YNHH for cis-platinum, vinblastine, and bleomycin therapy in managing gestational trophoblast disease.[109] The prompt institution of relatively low dose whole brain irradiation concurrently with multiagent chemotherapy may be beneficial in the treatment of brain metastasis and irradiation may provide local palliation to other sites of metastatic spread.[146]

It is the practice at YNHH to follow all patients who undergo evacuation of a hydatidiform mole with serial beta-HCG titers weekly starting from the time of the initial diagnosis of molar disease. Patients whose titers decline with evacuation of the mole and subsequently rise are treated with single agent chemotherapy provided there is no evidence of liver or brain metastases, the termination of the molar pregnancy was within 4 months of the rising titers and the UCG is less than 100,000 international units over 24 hours. Similarly patients whose beta-HCG titers plateau, i.e., 3 consecutive weekly determinations staying at the same level, are also treated with single agent therapy. Patients in the poor risk group with liver or brain metastases receive external beam irradiation to the involved area with the institution of combination chemotherapy.

Combination chemotherapy is repeated as soon as bone marrow recovery has occurred. This therapy is associated with significant toxicity and should only be undertaken by physicians trained in the management of the complications of combination therapy.

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Plutarch says that the life of a vestal virgin was divided into three portions; in the first of which she learned the duties of her profession, in the second she practiced them, and in the third she taught them to others. This is no bad model for the life of a physician; and as I have now passed through the two first of these times, I am willing to employ the remainder of my days in teaching what I know to any of my sons who may choose the profession of physic; and to him I desire that these papers may be given.

—The preface to "Commentaries on the History and Cure of Diseases," by William Heberden, 1802.

CSMS Professional Liability Insurance Program

Ninth Annual Report: August, 1980

AETNA LIFE & CASUALTY

ABSTRACT—Loss costs, which took a drastic turn for the worse last year, have escalated even more this year. Professional Liability Premiums for Connecticut physicians and surgeons will increase by 70% for the 1980-1981 account year.†

Aetna's figures indicate that in the 14 months ending June 1, 1980, the value of already reported losses rose by 66%, and the actuarial reserve for losses not yet reported increased by 122%. The projected loss per physician has increased over 400% from $1100 to $5600 between 1973 and 1979, with over two-thirds of the increase occurring during 1979, and continuing unabated into 1980.

Noting that the actual indicated rate increase (based on actuarial statistics to be filed with the State Commissioner of Insurance) is in excess of 85%, the Aetna said that the increase will be held down to 70% if the Society supports its members' involvement in innovative risk management programs already developed by CSMS during this past year.

This new Patient Risk Prevention Programming represents a major new Society initiative to get a handle on burgeoning claim activity. It includes a Claims Analysis component to enable physicians to review actual case episodes of maloccurrence, and to take appropriate action to prevent similar incidents from happening in their own hospital and office settings. The Aetna has allocated 1 percent of primary professional premium to fund this program as it is carried out by the Society and its members.

A major new feature of the CSMS-Aetna Program this year will be the option for physicians of choosing an alternative form of professional liability insurance, a "Claims-made" policy. This policy will *not* cover physicians for all incidents occurring in a particular policy year as under our "occurrence" type policy, but will cover only those *claims* actually made during that account year. The cost of the claims-made policy is much lower for the first two years of coverage, but when the physician retires or drops the policy for other reasons, he or she must then buy a final "reporting policy," to be protected for all past incidents which have occurred, but have not yet been reported. The cost of that final policy would approximate one fully mature year's premium at then current rates.

(The choice is whether you want to buy your "long tail" at today's rates as we do now, or at some future rates, a much grimmer prospect. The Society has long been on record as opposing "claims-made" coverage for our whole membership. However, for those few individuals in specific indicated circumstances, there is now a choice.)

Finally, the Aetna has increased the program's share of investment income from the loss reserves from 6% to 9% of total primary premium, reflecting last year's high interest rates. However, since this income is needed to reduce the program's present $12 million underwriting deficit, there will be no dividend returned to members this year.

Abstract prepared by CSMS staff

†LATE NOTE

At press time, CSMS can report that ongoing negotiations between CSMS staff and Aetna concerning the expense and commission portion of the rates will result in a small but significant reduction in the premium increase, subject to the Commissioner's approval.

PACKAGE PREMIUMS*
CONNECTICUT PHYSICIANS AND SURGEONS
OCCURRENCE POLICIES

Class	*Effective Date* *10/1/79*	*10/1/80*	*% Change* *10/1/79 to 10/1/80*
I	1,503	2,499	+66.3
II	2,540	4,260	+67.7
III	4,640	7,832	+68.8
IV	5,995	10,139	+69.1
V	7,459	12,633	+69.4
VI	8,924	15,129	+69.5
VIII	11,853	20,118	+69.7

*Includes Primary Professional Liability, SCOPE Personal and Professional, and Premises Liability. Limits: Class I and II: $1,100,000/1,300,000; Class III to VIII: $1,250,000/1,500,000.

CLAIMS-MADE POLICIES

Claims-made rates are established as a percentage of occurrence rates. The rate will be determined by applying the following factors to the occurrence rate for the appropriate classification:

1st year claims made	26%	3rd year claims made	81%
2nd year claims made	57%	4th year (mature) claims made	88%

Introduction

The Aetna is pleased to present the ninth Annual Report of the Connecticut State Medical Society's Professional Liability Program.

This report covers the period from October, 1971, to the present and is divided into six main sections:

ACCOMPLISHMENTS
IMPROVEMENTS
RISK MANAGEMENT/LOSS CONTROL
PREMIUM AND LOSSES
EXHIBITS
GLOSSARY

Program Objectives

Before presenting the specifics of this report, we believe it is worthwhile to review the objectives of the program:

— To provide a stable market for the purchase of professional liability insurance.

— To control or reduce losses insofar as possible and, thus, control and maintain premium costs at a reasonable level.

The purpose of this Annual Report to the Connecticut State Medical Society is to summarize the program accomplishments and the progress made towards achieving the objectives.

Accomplishments

The following are some of the accomplishments of the CSMS Program and the progress made on the major aspects of the program:

1. *Membership Participation*
   As of June 1980, 3,991 physicians and surgeons are participating in the Connecticut State Medical Society's sponsored Professional Liability Program. This represents approximately 90% of the eligible membership. As the program is a member benefit, this level of participation is indicative of the cooperative effort sustained through the years by the Connecticut State Medical Society and the Aetna.
2. *Risk Management*
   The key ingredient to the success of a professional liability program is to reduce and control claims and their associated costs. Since 1971, with the introduction of the CSMS Loss Control and Education Program, through 1980, with the development of a more sophisticated Risk Management Program, the CSMS Program has saved many claim dollars.

   The highly successful Claim Panels, along with seminars, brochures, videotapes and claim analysis studies have all contributed to making CSMS doctors more aware of the causes of malpractice claims and also the ways to reduce their exposure to such claims.

   Our past progress does not mean that we should diminish our risk management efforts. Rather, a renewed commitment and total involvement on the part of all health care providers is needed to continually improve the quality of medicine delivered to the citizens of Connecticut. Advances have been made, and are continuing to be made, but an ongoing cooperative effort is essential.
3. *Market Stability*
   Despite a countrywide market availability crisis during the 1970's, the CSMS Program enabled its members to enjoy a stable market. At the same time, in the first nine years of the program, only four members were denied coverage—all with the concurrence of CSMS.
4. *Coverage and Rating Improvements*
   Throughout the program's history, there have been changes and improvements designed to make the program responsive to the needs of physicians in Connecticut. Some of the major improvements include:
   New-To-Private-Practice Discounts
   "Med-Pak"
   Elimination of the Partnership/Corporation Surcharge
   Enlargement of the Classification System
   Availability of High Limits of Liability
   Defendant's Reimbursement at Optional Limits
   A Premium Finance Plan (CABS)
5. *Dividend Program*
   Since the inception of the program, Connecticut physicians have earned dividends in excess of $2,880,000. This is a direct reflection of the efforts to control the circumstances that give rise to malpractice incidents.

Improvements

Innovative and *Responsive*—these have been key words in the CSMS/Aetna cooperative efforts over the past several years. The CSMS Program is continually reviewed for ways to improve it. This year, there are additional improvements to the program.

Claims Made

The first improvement is the introduction of claims made, which will provide CSMS members a choice of coverage forms. CSMS members who select the Claims-Made Policy will continue to participate in the CSMS Dividend Program.

Claims-made rates are established as a percentage of occurrence rates. The rate will be determined by applying the following factors to the occurrence rate for the appropriate classification:

1st year claims made	.26
2nd year claims made	.57
3rd year claims made	.81
4th year (mature) claims made	.88

Reporting Policy - Prior Acts Coverage

Secondly, the availability of a Reporting Policy ("the long tail") is guaranteed to those physicians who purchase an Aetna Claims-Made Policy and subsequently terminate their claims-made coverage. There will be the option of a single payment or a three-payment plan. Once again, the rating of this Reporting Policy for prior acts is based on percentage factors:

Single Payment

Number of Years in Claims-Made Program	*Factor to be Applied to CURRENT Occurrence Rate*
1	.69
2	1.01
3 or more	1.10

Three Payments

Number of Years in Claims-Made Program	*Factor to be Applied to Occurrence Rate in Effect at Time of Installment*		
	Payment 1	*Payment 2*	*Payment 3*
1	.32	.24	.08
2	.56	.32	.08
3 or more	.64	.32	.08

Why is Aetna now offering claims made when we are still a proponent of the occurrence form? As the largest writer of occurrence form coverage for professional liability, we are responding to requests for this alternative form of coverage. By having lower premiums in the early years, claims-made coverage may have appeal for new physicians entering practice.

Market Guarantee - Sponsorship Commitment

When the CSMS/Aetna Program was implemented in 1971, there was an initial market guarantee of five years terminating on October 1, 1976; this original guarantee was extended for five additional years to expire on October 1, 1981. While the Aetna believes that progress has been made, much more can be accomplished as we continue to work together. The Aetna will continue its cooperative efforts with CSMS for an additional year until October 1, 1982.

Since we have had an excellent cooperative relationship, we believe that such a program extension will benefit both CSMS and the Aetna so that long-range plans and commitments may be made and implemented.

Physician and Surgeon Classification

Beginning with the 1976 Account Year, the classifications for physicians and surgeons were expanded from a few general categories to more than one hundred specialties.

By the end of 1980, preliminary data will be available on actual Connecticut program experience by classification. Aetna proposes that, in conjunction with the next semi-annual meeting, we review the actual experience under the program to determine if future classification changes are warranted.

Conclusion

The success of any positive, long-term program depends on communication and working together toward a common goal. With the past program improvements and those mentioned above, the CSMS/Aetna Program will continue to be a positive benefit for all concerned parties.

Risk Management/Loss Control

Risk management may be defined as a detection system that is designed to predict failures due to systems or persons and prevent them from happening. Physicians who are members of an organized hospital medical staff are in an excellent position to predict when a mistake or negligence is likely to occur—and to take measures to prevent it from happening.

Consistent with the need and desirability to involve physicians directly, Aetna and the Professional Liability Committee have recommended to the CSMS leaders and to hospitals which Aetna insures a cooperative effort known as the Patient Injury Prevention Program. This program will include:

- An Insurability Committee to develop a program of review by the Medical Society of new applicants and present individual insureds whose past claim experience suggests they have above average risk to future claims because of
    - a. Past Claim Experience
    - b. Method of Practice
    - c. Impairment
- A Claim Analysis component that will develop a program to enable physicians to review case episodes of patient injury and take whatever action may be necessary to prevent similar type losses.
- A Continuing Medical Education component whose purpose will be to encourage physicians to become involved in the implementation of individual risk management activities.

Implementation is expected to begin this fall.

The discussion to date suggests an answer to the medical care aspects of malpractice may lie in fostering a funded program with 1% of the primary professional liability premium for research and clinical analysis of the causes of malpractice. The thrust suggested involves identification of violations of scientific principles or deviation from accepted management of health care and at improving the approach of physicians in the human as well as medical aspects of patient care.

The program uses a retrospective, concurrent and prospective approach based on scientific principles. The 1% fund may be used to provide educational materials or conduct educational sessions in order to correct an identified patient injury exposure.

Individual Risk Management

In sharing with Aetna the responsibility for underwriting decisions involving non-renewal of physicians, surcharging and large deductibles, the Professional Liability Committee is involved in assessing the claims potential of individual CSMS members. Last year, eight physicians were identified and appeared before the Committee to discuss their individual claim situations. The underwriting action recommended by the Committee was adopted by Aetna in each case. This year two physicians have appeared and the recommendations of the Committee were as follows:

a) limitation of practice
b) one-year probation for non-renewal

Claim Activity

In the 1979 Annual Report, we noted 1,418 cases under the program as of July, 1979. During the past eleven months, the cumulative number of claims increased by 265 to 1,683 as of June, 1980. The corresponding increase in reserved and paid claims during the same period on reported losses was $8,826,708.

The number of claims per account year and the cumulatived number per account year are shown below:

Table I

As of	*Arising Claims (per account year)*	*Arising Claims (cumulative)*
7/72	20	20
7/73	81	101
7/74	132	233
7/75	187	420
7/76	249	669
7/77	251	920
7/78	231	1,151
7/79	267	1,418
6/80	265	1,683

The number of suits pending and the numerical increase each year are shown below:

Table II

As of	*Suits Pending*	*Numerical Increase*
6/76	176	—
6/77	276	100
6/78	317	41
6/79	464	147
6/80	535	71

A review of the data presented in the semi-annual report to the Society reflects that over the past 24 months the average cost per claim, including those closed without payment, has increased from $10,000 to $18,000.

The severity trends in Connecticut are expected to continue due to the inflationary cost of health care and the reluctance of the courts to set aside or reduce awards.

In the past year eleven cases were brought to trial. Six were defendant verdicts, one plaintiff verdict, two settled during trial, one withdrawn during trial and one as yet undecided by the Court.

Claim Defense Panels

The mechanism of peer review is the single most effective tool to assess the impact of patient injury on loss dollars. The panels embody the partnership spirit of the program by providing physicians the opportunity to share in the responsibility for the disposition of the cases. More than 375 cases have been reviewed through the expertise of over 850 doctors who have participated in one or more panels. The vote continues to reflect that approximately half of these cases have some merit on the medical facts alone and should be settled. To date, 40% of the cases reviewed have been settled, 17% withdrawn or tried, with 43% pending trial or disposition. The cooperation of the Society membership in this activity has been exemplary and is expected to continue.

Educational Activity

Aetna's Loss Control and Education Program was initiated concurrently with the beginning of the CSMS Professional Liability Program in 1971. It was developed and evolved from a mutual concern on the part of the Society and the Aetna for the rising number of claims and the increasing severity of losses. Its tools include the use of videotapes, printed material, speakers, special studies, claim tracking and analysis, and claim review panels—all directed at identification of the causes and prevention of malpractice.

Aetna will continue its broad based program of educational activities through the use of innovative and more specific programs, developing a growing number of audiovisual aids, and implementing the program through claim-oriented representatives and a Medical Section of the company.

Legislative Activity

An analysis of the existing statutes and common law in Connecticut reflects a situation somewhat more favorable to physicians than in some other states.

Among the measures considered this past year was a "Collateral Source" provision that would prevent a plaintiff from collecting an amount equal to the cost of health care as part of compensatory damages, if this amount has already been paid by a third-party carrier. It was agreed these sums should simply be evidence allowed for the jury to consider and not a bar to recovery. A second bill considered will allow for malpractice judgment to be satisfied by structured settlements in periodic payments. The intent is to revert funds in the event of death, to prevent windfall profit to others than the patient.

Pursuit of these bills and a mandatory screening process were postponed, since there was little likelihood they would pass in the legislature. Instead, attention focused on the deficiencies in the existing peer review immunity legislation. Through effective lobbying efforts, an acceptable revision of the statute was passed.

The Society, the Hospital Association and the Aetna will continue to explore options for meaningful tort reform in formulation of a joint legislative package for next year.

Conclusion

Throughout the turbulent 70's, the CSMS/Aetna Program has provided a stable and available professional liability insurance market for Connecticut physicians. Aside from diligent practice, the only preventative measures are simply attention to and consideration of the causes and prevention of malpractice. The two, protection and education, are the essence of the Aetna Program sponsored by the Society.

Premium and Losses

During the last 12 months, the claim climate in Connecticut has continued to deteriorate. While the number of claims continues to increase, the average settlement value across the country is reaching unprecedented heights, especially in Connecticut. This rapid escalation in loss costs compels us to increase rates again this year.

Rates

The actuarial indicated rate increase for the professional liability coverage for the coming year is in excess of 85%. However, if the Society makes a commitment to implement the Patient Injury Prevention Program, an expanded and innovative Risk Management Program, the rate increase will be reduced to 70%. This reduction in the amount of the increase also recognizes that the company's expenses will not increase proportionately.

Premises liability rates for office exposures will remain the same. Personal excess liability coverage under SCOPE will also increase, with the amount of that increase varying based on the individual exposures of each doctor.

The combined effect of these changes will be an increase of approximately 68.8%, ranging from 66.3% for a Class I physician to 69.7% for a Class VII. Exhibit I shows the approximate package premiums by class, with the percentage change for each class.

Trends

The rate indication this year included an annual trend (frequency and severity) assumption of 16.9%; that is, our loss costs were projected from past years to determine what would be needed next year by increasing those loss costs by 16.9% per year. This trend is established by reviewing our countrywide loss per doctor over the past 11 years and measuring the average increase year to year.

A similar calculation using the year-to-year change in loss per doctor for Connecticut produces an average change of 26% per year. Exhibit II shows Connecticut and countrywide trends, as well as the amount of loss per doctor anticipated in next year's rates.

Exhibit II

LOSSES PER DOCTOR

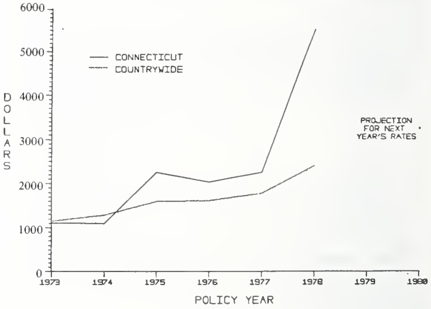


Exhibit I

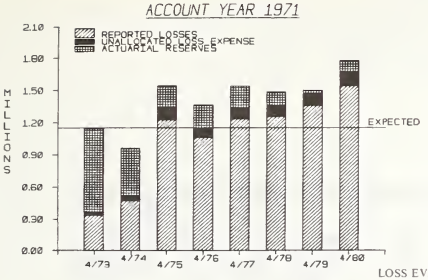
PACKAGE PREMIUM*
CONNECTICUT PHYSICIANS AND SURGEONS

	EFFECTIVE DATE							% CHANGE
CLASS	10/1/71	10/1/75	10/1/76	10/1/77	10/1/78	10/1/79	10/1/80	10/1/79 TO 10/1/80
I	445	913	1021	1023	1220	1503	2499	+66.3
II	716	1579	1754	1714	2050	2540	4260	+67.7
III	1568	2872	3173	3239	3733	4640	7832	+68.8
IV	2059	3800	4192	4173	4817	5995	10139	+69.1
V	2549	4728	5212	5189	5939	7459	12633	+69.4
VI		5656	6231	6203	7160	8924	15129	+69.5
VII		7511	8270	8231	9503	11853	20118	+69.7

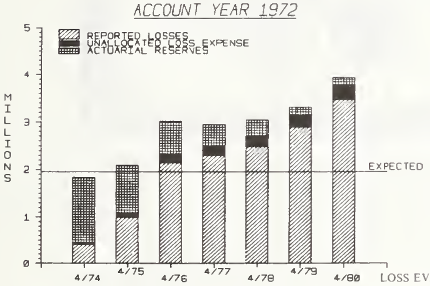
*INCLUDES PRIMARY PROFESSIONAL LIABILITY, SCOPE PERSONAL AND PROFESSIONAL, AND PREMISES LIABILITY.

The exhibit on the facing page portrays the loss experience of the program as it has changed over the years. For each account year, the level of losses is shown as it appeared at each dividend evaluation. The last bar on the right of each graph represents the latest estimate of the losses as of April 1, 1980. Losses are now estimated to exceed our earlier projections of total loss at the time the rates were established.

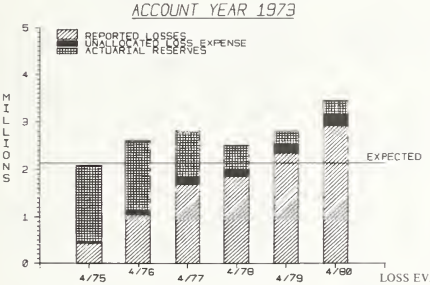
CSMS LOSS EXPERIENCE BY ACCOUNT YEAR


ACCOUNT YEAR 1971

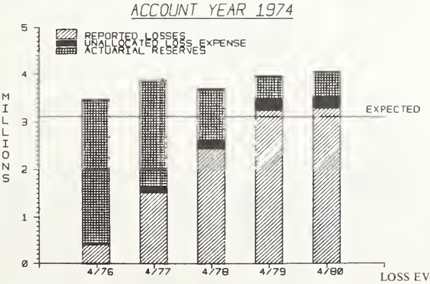
LOSS EVALUATION DATE


ACCOUNT YEAR 1972

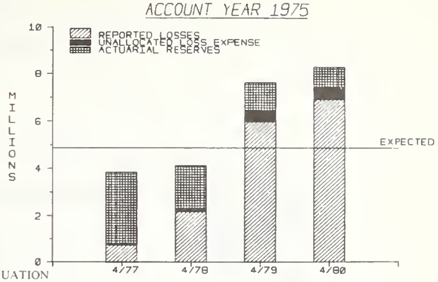
LOSS EVALUATION DATE

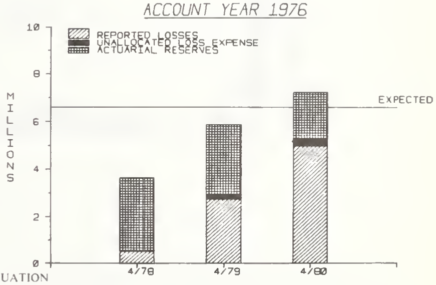

ACCOUNT YEAR 1973

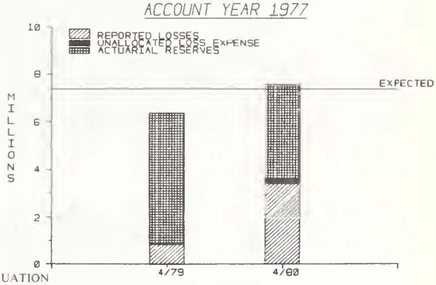
LOSS EVALUATION DATE


ACCOUNT YEAR 1974

LOSS EVALUATION DATE


ACCOUNT YEAR 1975


ACCOUNT YEAR 1976


ACCOUNT YEAR 1977

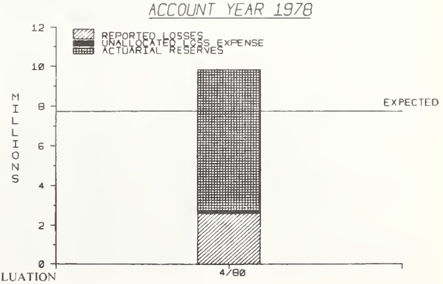
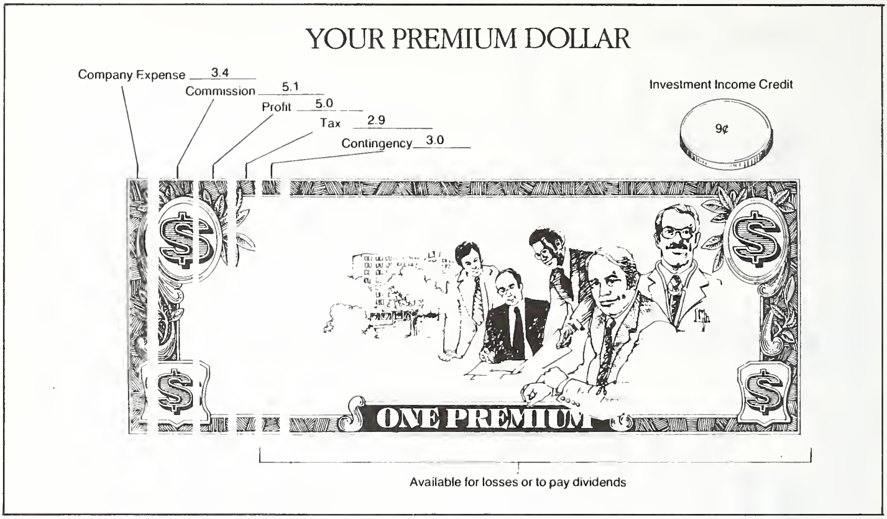

ACCOUNT YEAR 1978

Exhibit III



Expenses

The expense provisions for rates for the coming year are detailed in Exhibit III. The provision for loss (including settlement expense) is 80.6%; of the remaining 19.4%, 3.4% is for company administrative expense, 5.1% for agents' commissions, 2.9% for premium taxes, 5.0% for company profit and 3.0% for contingency. Thus, 83.6% of the premium dollar is available to pay claims and their associated expenses or is available to return to CSMS members as dividends.

Dividends

Exhibit IV, Parts 1 and 2, shows the loss experience of the program thus far and the dividend calculation. As can be seen, losses for each year of the program now exceed the amounts expected when rates were established. Cumulatively, the loss deficit now totals approximately $12,000,000. Thus, no dividend has been declared for this year.

The Investment Income credit, initially included with last year's dividend calculation, provides a fund to offset loss deficits or to be returned as a dividend when the cumulative program experience is profitable. Last year, the Aetna allocated 6% of the 1978 Primary Professional premium to this fund; this year, the amount of the Investment Income credit was increased to 9% of the 1979 Primary Professional premium. This reflects the higher interest rates in effect when the 1979 premium was collected. This fund now totals $1,679,503.

Exhibit IV, Part 2
CALCULATION OF DIVIDEND - CSMS

Loss Savings:	1. Total Loss Savings (II.e)	$ (11,993,013)
	2. Loss Savings Previously Returned (V.a.)	99,345
	3. Net Total Loss Savings	(12,092,358)
Expense Savings:	1. Total Expense Savings (III.b)	3,573,321
	2. Expense Savings Previously Returned (V.b)	2,599,745
	3. Net Total Expense Savings	973,576
Investment Income:	1. Total Investment Income (IV)	1,679,503
	2. Investment Income Previously Returned (V.d)	0
	3. Net Total Investment Income	1,679,503
Indicated Dividend:	Net Total Loss Savings	(12,092,358)
	Net Total Expense Savings	973,576
	Net Investment Income	1,679,503
		(9,439,279)
	Dividend Due:	$0

Exhibit IV, Part I
CONNECTICUT STATE MEDICAL SOCIETY
DIVIDEND CALCULATION @ 4/1/80

	1971	1972	1973	1974	1975	1976	1977	1978	1979	1971-1978 Cumulative
I. Collected Premium	1,685,832	2,303,432	2,619,569	4,840,838	7,072,792	9,041,525	9,414,679	9,953,991	12,025,156	46,932,658
a. Loss Provision	1,097,477	1,499,534	1,713,198	3,112,659	4,873,154	6,609,355	7,371,694	7,744,205		34,021,276
b. Expense Provision	588,355	803,898	906,371	1,728,179	2,199,638	2,432,170	2,042,985	2,209,786		12,911,382
II. Actual Losses										
a. Reported	1,538,520	3,462,185	2,914,045	3,287,756	6,908,283	4,965,244	3,417,094	2,614,019		29,107,146
b. Actuarial Reserves	96,092	131,296	254,098	469,561	770,934	1,790,222	3,652,895	6,609,450		13,774,548
c. Loss Adjustment Expense	140,577	334,194	272,460	296,828	583,620	459,372	473,689	571,855		3,132,595
d. Total	1,775,189	3,927,675	3,440,603	4,054,145	8,262,837	7,214,838	7,543,678	9,795,324		46,014,289
e. Loss Savings (I a - II d)	(677,712)	(2,428,141)	(1,727,405)	(941,486)	(3,389,683)	(605,483)	(171,984)	(2,051,119)		(11,993,013)
III.										
a. Actual Expenses	424,830	587,376	662,750	1,282,822	1,527,721	1,573,225	1,572,251	1,712,086		9,343,061
b. Expense Savings (I b - III a)	163,525	221,522	243,621	445,357	671,917	858,945	470,734	497,700		3,568,321
IV. Investment Income Credit								597,239	1,082,264	1,679,503
V. Paid Back to Date										
a. Loss Savings	0	0	0	0	0	99,345	0	0		99,345
b. Expense Savings	121,363	66,238	0	0	0	2,412,144	0	0		2,599,745
c. Interest on Savings	0	0	0	0	0	183,323	0	0		183,323
d. Investment Income Credit										0
										2,882,413

GLOSSARY

Accident Date - Date on which a procedure was performed which results in a claim being presented.

Account Year - The annual period during which policies are effective—for example, in Connecticut Account Year 1976 is the period 10/1/76 to 10/1/77.

Actuarial Reserve - Funds established to pay liabilities not identified by existing claim file.

Allocated Loss Adjustment Expense - Expense items such as attorney fees, medical examination costs, etc., which can be attributed to a specific claim.

CABS (Commercial Account Billing System) - Method of paying premiums annually, quarterly, or monthly.

Classification - Category of physicians specialities.

Class Relativity/Differential - Rating factor applicable to produce the rate for a given classification.

Coverage - See Coverage Terminology page.

Developed Incurred Losses - Total dollars ultimately payable on both reported and unreported claims.

Effective Date - Date on which policy coverage begins.

Expected Loss Ratio - Ratio of losses to premiums which will permit payment of all expenses and realization of desired underwriting profit.

Expense Savings - Difference between anticipated and actual company expenses (administrative, commissions, taxes, and profit).

Experience - Information about past losses and expenses.

Experience Period - As used in making rates, the period of time, calendar years, from which loss and exposure data is used to make rates.

Exposure - A unit of one doctor insured for one year.

Frequency - Number of claims.

IBNR (Incurred But Not Reported) - Claims which have happened under a past or current policy, but currently not reported.

Increased Limits Factor - Rating factor applied to basic limit rates to produce rates for higher limits of coverage.

Investment Income - Income which is the result of investments on collected premiums.

Long Tail - The time span between when a claim occurs and is reported and paid.

Loss Savings - Difference between anticipated and actual loss expense, including IBNR.

Participation/Dividend - Distribution of loss and expense savings and investment income to policyholders.

Policy Year - Year in which policy coverage is effective.

Primary Limits - Liability limits of 100,000 per claim/ 300,000 aggregate for physicians of 250,000/500,000 for surgeons.

Reported Loss - Loss for which an individual claim file has been established.

Scope - Excess limits of coverage effective above primary limits for professional and personal liability coverages.

Severity - Average claim payment or reserves.

Underwriting Losses - Negative profits on insurance operations, i.e., outgo (claims and expense) exceed income (premium).

COVERAGE TERMINOLOGY

Occurrence Coverage - Coverage is provided the insured for acts or omissions that *occur during the policy period,* no matter when the claim is presented.

Claims-Made Coverage - Coverage is provided the insured for claims first *made during the policy period,* which arise from acts or omissions that occur on or after the retroactive date of coverage.

> *Retroactive Date* - The month, day and year stated in the policy, on or after which an incident must occur, in order for claims arising from that incident to be covered, if reported during the Claims-Made Policy period. The retroactive date usually is the date an insured *first* entered a claims-made program.
>
> *Extended Reporting Period Option* - The Claims-Made Policy guarantees the insured this option. If claims-made insurance is terminated either by cancellation or non-renewal (for example, insured retires, changes claims-made carriers or switches to the occurrence coverage form), the Named Insured has the right, upon payment of the appropriate additional premium, to have issued a policy which provides a reporting period, during which claims which would have been covered by the claims-made insurance may be reported.
>
> This option must be exercised in writing not later than thirty (30) days after the termination date of the claims-made insurance. The exercise of this option results in "prior acts" coverage.

Prior Acts Coverage - Prior acts coverage responds to the long "tail" of professional liability claims which may arise from incidents which occurred during the time claims-made coverage was in effect, but which are not reported/made until *after* claims-made coverage is terminated.

Prior acts coverage is provided via "Reporting Policy" and may be purchased in one installment (a single reporting period) or three installments (two annual reporting periods and one final reporting period).

Reporting Policy - The coverage form used to provide prior acts coverage. This policy provides additional time—the reporting period—during which the insured can report claims arising from acts or omissions during the coverage period—the time claims-made coverage was in effect.

> *Coverage Period* - The period of time stated in the declarations, beginning with the retroactive date and ending with the date stated as the "Termination Date of Claims-Made Coverage" (i.e., the time claims-made coverage was in effect).
>
> *Termination Date of Claims-Made Coverage* - The month, day and year stated in the policy on which the insured's previous claims-made coverage terminated.

Reporting Period - The period of time stated in the declarations for reporting claims or suits alleging injury arising out of a medical incident during the coverage period.

CSMS Patient Risk Prevention Plan

CSMS COUNCIL

ABSTRACT—Although many other factors contribute to the rising cost of malpractice insurance, it is recognized that medical maloccurrence and malpractice is the substrate on which the problem grows. The Aetna's reduction of an actuarially indicated rate increase reflects a credit for a commitment by the Society to encourage participation of its members in augmented risk management and patient injury prevention activities developed by CSMS this past year with Aetna.

The plan includes an innovative patient injury prevention component utilizing actual malpractice episodes to identify and to motivate elimination of critical elements of patient risk. A second component introduces medical peer judgement to decisions concerning the insurability of individual physicians thought to present an abnormal risk to patients and to the actuarial soundness of the insurance program. A third component provides incentive for voluntary participation in both new and existing risk management activities.

GOAL A

Reduce the incidence of patient injury attributable to cognitive, clinical, or management deficits in the provision of patient care by physicians and other professionals in both institutional and ambulatory settings.

Program A: Patient Injury Prevention Program

Component 1:

A CSMS endorsement of JCAH Quality Assurance Standards; and a request to hospitals and to Specialty Sections, seeking physician liaison officers to the CSMS Professional Liability Committee's Patient Injury Prevention Program.

Mechanism a: Council endorsement of JCAH Quality Assurance Standards. (See Figure 1)

Mechanism b: Professional Liability Committee charge to a Patient Injury Prevention subcommittee (already in existence but expanded to specialty sections and liaison officers). (See Figure 2)

Mechanism c: Council to authorize a letter to Hospital Chiefs and to CSMS Section Presidents, seeking PIP Liaison Officers to Society's Committee on Professional Liability. These might be Chiefs, DMEs, Audit Chairman, Section Officers, etc., but they must be members of standing committees of the organized staff involved in Peer Review.

Quality Assurance

JCAH: 1980 Accreditation Manual for Hospitals, p.151

PRINCIPLE

The hospital shall demonstrate a consistent endeavor to deliver patient care that is optimal within available resources and consistent with achievable goals. A major component in the application of this principle is the operation of a quality assurance program.

STANDARD

There shall be evidence of a well-defined, organized program designed to enhance patient care through the ongoing objective assessment of important aspects of patient care and the correction of identified problems.

Figure 1

Component 2:

A Claims Analysis System to process and to promulgate Aetna-supplied malpractice episodes as quality sensors and motivators to hospital staffs, clinics, specialty sections, non-hospital oriented physicians, CSMS membership at large, etc., through letters, advisories, newsletters, and the Journal.

Mechanism a: The Claims Analysis System is to be developed by the PIP Program Subcommittee, relying on consultation with Specialty Sections and Hospital Staff Liaison Officers to analyze episodes and to identify critical clinical or management elements for retrospective, concurrent, or prospective studies in the hospital or other settings. PIP Program Subcommittee expenses to be submitted to Aetna's Risk Management and Loss Control Fund.

At its August 14, 1980 meeting, the Society's Council approved this plan and its implementation. The Plan was presented to the Council with the endorsement of Lawrence B. Ahrens, M.D., Chairman, Committee on Professional Liability; Donald L. Brown, M.D., Chairman, Committee on Continuing Medical Education; Marvin Garrell, M.D., Chairman, Committee on Continuing Care and Rehabilitation and Robert J. Brunell, M.A., CSMS Assistant Executive Director for Educational and Scientific Activities.

Mechanism b: Promulgation of episodes and analyses in sterilized format to target groups through letters, advisories, newsletters or Journal features.

Mechanism c: Aetna funding of special PIP Program CME formats developed and/or requested by hospitals and by city, county, specialty or state societies, and approved by PIP Program Subcommittee.

Mechanism d: Develop program evaluation methods for hospital use to give feedback to PIP Program Subcommittees on program effectiveness.

Charge to the PIP Program Subcommittee of the Professional Liability Committee

The Professional Liability Committee shall appoint a Patient Injury Prevention Program Subcommittee. The Subcommittee shall be chaired by the Chairman of the Committee on Professional Liability, and shall include the Chairmen of the Committee on Continuing Medical Education, the Committee on Continuing Medical Care and Rehabilitation, and the Committee on Hospitals or their nominees; four CSMS members drawn from among the PIP Liaison Officers from hospital staffs and CSMS Specialty Sections; and two other CSMS members. The Subcommittee may in the course of its activities call upon consultants and guests drawn from among other Society committees, Specialty Sections, the hospital staffs, the Aetna Professional Liability Division, and the CHA.

The function of the Subcommittee will be to carry out the CSMS-Aetna Patient Injury Prevention Program approved by the Council; including a system for the analysis of professional liability claims, the promulgation of resulting studies to appropriate target groups; the promulgation and analysis of the Aetna's forthcoming closed claim study; and the timely evaluation of the program's effectiveness.

The goal of the Subcommittee is to reduce the incidence of patient injury attributable to cognitive, clinical, or management deficits in the provision of patient cared by physicians and other professionals in both institutional and ambulatory settings.

The Subcommittee shall make timely reports on the progress of the PIP Program to the Committee on Professional Liability, the Committee on Continuing Medical Education, the Committee on Continuing Medical Care and Rehabilitation, and the Committee on Hospitals, through their respective Chairmen, as well as to the Council of the Society.

Figure 2

Component 3:

Analysis of the Aetna's Closed-Claim Study now in progress, with a view to identifying and characterizing risk concentrations for the purpose of focusing patient injury prevention studies on indicated groups and procedures.

Mechanism a: After publication by Aetna and review by the Professional Liability Committee, circulate the Study through the PIP Program Subcommittee to Counties, Specialty Sections and PIP Liaison Officers, to gather proposals for new PIP Program studies directed to indicated target groups and procedures.

Mechanism b: Select proposals and develop studies and advisories for promulgation through PIP Program channels.

Mechanism c: Apply evaluation methods above (Component 2d) for assessment of effectiveness.

*****

GOAL B

Provide additional medical input to the Professional Liability insurance underwriting process and to underwriting standards, for the purpose of reducing the incidence and severity of both actuarial and patient risk.

Program B: Individual Risk Management

Component 1:

An ongoing insurability review program for individual physicians deemed to present an abnormally high risk to the program because of: claim experience, method of practice, or impairment. This involves screening efforts of both Aetna and the Society, peer review and insurability hearings; and recommendations by CSMS to Aetna of appropriate underwriting action options, with due process and appeal safeguards built in. Such options may include:

1. Individual counseling by Medical Society members
2. Curtailment of specific medical/surgical procedures
3. A Surcharge between 25% and 100% of the Professional Liability premium
4. A deductible from $5,000 to $25,000 per claim, excluding defense costs
5. Declination of a new applicant or non-renewal of a current insured for Professional Liability Coverage.

Options 3, 4, and 5 are subject to a final decision by Aetna.

Mechanism a: Activate the Insurability Review Subcommittee of the Professional Liability Committee (already instituted at the 6/80 Council) to develop joint Insurability Review guidelines with Aetna underwriters, for action by Professional Liability Committee and Council.

Mechanism b: Implement Insurability Review Program using the Professional Liability Committee for insurability hearings, and the new Insurability Appeals Panel (already instituted at 6/80 Council) for appeals.

*****

GOAL C

Involve more physicians in improved patient injury prevention activities to achieve indicated improvements in cognitive, clinical and management skills.

Program C: CME for Patient Injury Prevention

Component 1:

CSMS encouragement to physicians to become involved in various patient risk management activities in their hospitals and clinics, in their various medical societies, and in their private offices.

Mechanism a: Promotion through newsletters and Journal of PIP Program activities and results, and of special PIP Program CME activities in Hospitals and Societies (Program A, Component 2c)

Mechanism b: Society recognition in its Journal and at its House of Delegates meetings of hospital and Society PIP Program Studies proved effective through the evaluation process. (Program A, Component 2d)

Component 2:

Continuation and sophistication of present District Review Panel activities by CSMS, and of loss control education activities by Aetna.

Mechanism a: Meetings between District Review Panel Chairmen and Aetna to enhance the educational value and physician participation in Review Panel meetings.

Mechanism b: Consultation by Aetna Risk Management and Loss Control staff with hospital PIP Program Liaison Officers to upgrade present materials and programs.

Mechanism c: Continuation of CSMS support for CSMA-Aetna Pocket Calendar-CME Record distribution.

CHANGES IN THE MECHANISMS FOR ACCREDITING MEDICAL EDUCATION are being recommended by the Board of Trustees in discussions it has initiated with the parent organizations of the Coordinating Council on Medical Education and the liaison committees. The House of Delegates adopted a report outlining the proposed changes and authorizing the Board to continue with formal negotiations and to implement the revisions. In addition to the AMA, parent organizations of the CCME are the American Board of Medical Specialties, American Hospital Assn., Assn. of American Medical Colleges, and Council of Medical Specialty Societies.

The Board reported that the concept of coordinating the accreditation programs of undergraduate, graduate, and continuing education "simply is not viable" because of differing needs at each stage and that each level requires a separate accrediting organization. It called for reconstitution of the CCME as an advisory forum, noting that the CCME's other sponsoring organizations had reached the same conclusion independently.

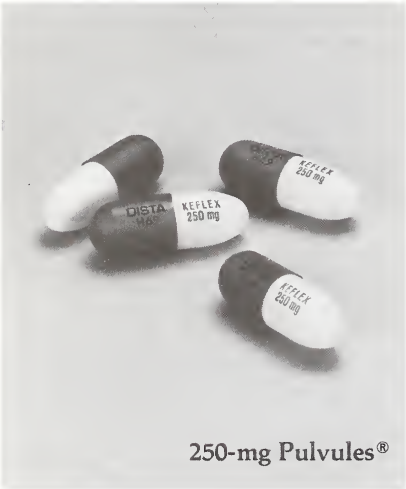
In the discussions the AMA will consider methods of establishing a single mechanism to replace the current dual system of accrediting continuing medical education. Such a mechanism, the Board said, must include intrastate accreditation by state societies, an appropriate role for specialty societies, a clear definition of what constitutes a policy matter, continued right of approval on policy matters, and assurance of the AMA's role.

Accreditation of graduate medical education should be modified to make residency review committees responsible for actual accreditation decisions, the report said, and to change the functions of the Liaison Committee on Graduate Medical Education to a policy development and appeals role. The Board said no changes would be needed in the accreditation of undergraduate education.

The House also called for continued support of voluntary continuing medical education and asked state associations and specialty societies to support a moratorium on additional mandatory CME and mandatory recertification programs.

—AMA *Newsletter,* Vol. 12, No. 26, July 28, 1980

easy to take



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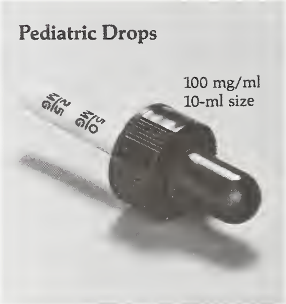

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Pain, Discomfort and Humanitarian Care

ORGANIZED BY: INTERAGENCY COMMITTEE ON NEW THERAPIES FOR PAIN AND DISCOMFORT

Assisted by the Office for Medical Applications of Research, NIH

Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

The Department of Health, Education and Welfare in collaboration with the White House has identified chronic pain and terminal illness as areas needing increased emphasis and awareness in our country. The Interagency Committee on New Therapies for Pain and Discomfort is serving as the federal focal point for planning activities in research, education and the organization of health care services. In order to document the scientific base for future activities, a "Conference on Pain, Discomfort and Humanitarian Care" was held at the National Institutes of Health on February 15-16, 1979. This conference was organized by the Interagency Committee to review the present status of scientific information and to identify areas which should receive additional attention.

As part of the meeting, a "consensus development" panel on "The Management of Pain and Discomfort in the Terminally Ill" was held on February 16. The consensus development program at NIH brings together biomedical research scientists, practicing physicians, consumers, and others in an effort to reach general agreement on the efficacy and safety of a medical technology.

Topics addressed during the consensus development panel included "The Care of the Aged," "Death and Dying," "The Hospice Approach to Terminal Illness," and "Pain and Well-being: A Challenge for Biomedicine." In the discussion period, the panel agreed on the following statements:

1. Biomedical scientists recognize that compassion plus knowledge and technical skills are required to manage the aged person and the terminally ill patient. The physician with this humanitarian approach will be able to shift his emphasis from keeping the patient alive ("curing") to allowing the patient to die with dignity ("caring").
2. The chronic pain experienced by many persons afflicted with long-term or terminal illnesses is a multidimensional, hierarchical phenomenon that is influenced by somatosensory, affective, cognitive, social and behavioral factors. The treatment of this suffering requires an integrated approach exemplified by the hospice model which addresses the patient's physical, mental, social and spiritual needs.
3. Important principles for the management of terminally ill patients include the following:
   - Chronic pain should be treated with continuous, oral narcotic or other analgesics individually titrated to keep the patient in the therapeutic range.
   - Antinauseants, antibiotics, stool softeners, corticosteroids, and antidepressants should be used as necessary for symptom management. Because many patients are dying at home, a contingency plan should be developed for medical emergencies to prevent inappropriate hospital admissions, which often include excessive diagnostic studies and therapies.
   - The patient and the family should be treated as a unit in order to lessen the loneliness, guilt, anger, and conflict that often accompany death.
4. A number of professionals, in addition to practicing physicians, contribute to the care of the dying

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NIH Consensus Development Conference Summary Vol. II

EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

patient; nurses, social workers, rehabilitation specialists, nutritionists, pharmacists, spiritual counselors, volunteer aids, health administrators, etc. are important members of this health team.

5. The principles of the care of the aged and terminally ill are compatible with the goals of the existing health care system in the United States. In order to define an effective mechanism for delivering these services, the role of the traditional medical center, of the health care professional, and of society will have to be reassessed in light of the hospice concept.
6. Clinical research is required to define more clearly issues related to the aged and terminally ill. This research should include studies of the following:
    The epidemiology of aging and death in the United States; the mechanism, measurement, and management of chronic pain in these conditions; the efficacy of bereavement counseling; and the identification of the psychological and social issues related to the aged and the terminally ill.
7. Practicing physicians and nurses need to be educated in chronic pain and cancer pain diagnosis and management. The curricula of medical and nursing schools should include factual material and clinical experience in pain management, the problems of the aged, and care of the dying.

Panel members for the Consensus Development Conference were: Diane Fink, M.D., Division of Cancer Control and Rehabilitation, National Cancer Institute, Chairperson; Paul F. Engstrom, M.D., American Oncologic Hospital, Philadelphia, rapporteur; Robert N. Butler, M.D., Director, National Institute on Aging; Melvin J. Krant, M.D., University of Massachusetts Medical Center; William Fischer, M.D., Hospice, Inc., New Haven; Thomas West, M.D., St. Christopher's Hospice, London; and Lorenz K.Y. Ng, M.D., Division of Research, National Institute on Drug Abuse.

Sponsors of the conference were: National Institute of Mental Health, Alcohol, Drug Abuse and Mental Health Administration (ADAMHA); National Institute on Aging, NIH; National Cancer Institute, NIH; National Institute of Neurological and Communicative Disorders and Stroke, NIH; National Institute of Dental Research, NIH; National Institute on Drug Abuse, ADAMHA; Bureau of Drugs, Food and Drug Administration, (FDA); Office for Medical Applications of Research, NIH; Fogarty International Center, NIH.

THE COLLEGE OF PHYSICIANS & SURGEONS, COLUMBIA UNIVERSITY

Postgraduate medicine courses for September through November:

Renal Biopsy in Medical Diseases of the Kidney, Sept. 29 to Oct. 3, 1980. Fee: $400 (resident's fee: $200) includes syllabus, slides, luncheons. (35 credit hours). Conrad Pirani, M.D.

Advances in Surgical Pathology, Oct. 6-8, 1980. Fee: $300 (or $125 per day); resident's fee: $150 (or $60 per day) includes syllabus and luncheons. (24 credit hours). Cecilia Fenoglio, M.D. and Luciano Ozzello, M.D.

Symposium on the Optic Nerve, Oct. 9 and 10, 1980. 11th Annual Course of the Edward S. Harkness Eye Institute. Fee: $200 (resident's fee: $100) includes luncheons. (14 credit hours). Myles M. Behrens, M.D.

20th Annual Review Course in Obstetrics and Gynecology, Oct. 20-24, 1980, Fee: $375 (resident's fee: $200). 37 credit hours, Category 1, AMA's P.R.A.; 35 Cognates, A.C.O.G.; 33½ credits, A.A.F.P. Raymond Vande Wiele, M.D.

Basic Medical Hypnosis, Oct. 27-30, 1980. Fee: $400 (resident's fee: $300). (32 credit hours). Herbert Spiegel, M.D., Barbara DeBetz, M.D., David Spiegel, M.D.

Postgraduate Review Course of Procedures Used in the Practice of Allergy, Nov. 5-7, 1980, at the N.Y. Acad. of Med. Cosponsored by the Amer. Acad. of Allergy, R.A. Cooke Inst. of Allergy of St. Luke's-Roos. Hosp. Ctr. Fee: $250 (resident's fee: $125) includes luncheons. (22 credit hours). Michael Grieco, M.D., William Kniker, M.D.

Postgraduate Review Course in Neuroanatomy, Neurophysiology, and Neuropharmacology, Nov. 13, 1980 - April 4, 1981 (20 Sats., 9:30 - Noon), Fee: $420 (resident's fee: $210). (42 credit hours). Edgar M. Housepian, M.D.

Names of Course Directors follow each listing. All courses approved for Category 1 credit, AMA's P.R.A. Contact: Dr. Elizabeth C. Gerst, Dir., CME, P&S, 630 West 168th Street, New York, N.Y. 10032; telephone: (212) 694-3682.

Commission on Hospitals and Health Care: An Update

VINCENT A. PROTA, M.S.

Connecticut hospitals have the somewhat questionable distinction of being located in a state with perhaps one of the most centralized systems of hospital regulation in the nation. Now while there is nothing wrong with a centralized regulatory system per se—indeed, it can have its advantages in terms of speed when operated properly—problems can arise when the persons at the pinnacle of such a system adopt a "we-versus-they" attitude with regard to the persons or institutions they are regulating. This is exactly what has occurred in the relationship between the state's 36 acute care hospitals and the Connecticut Commission on Hospitals and Health Care (CHHC).

When the CHHC was created in 1973 by the General Assembly, the goal was to establish a governmental unit that could work with hospitals to control health care costs. As the lawmakers themselves put it in the introduction to the statute which established the CHHC:

> "The General Assembly finds that the mutual interest of the state and the administrators and trustees of health care institutions and facilities within the state for the provision of health care to our citizens and the control of the costs of such health care creates a need for a partnership to provide for the effective promotion of such mutual interest."

While hospitals and health care institutions in particular were targeted in the statute, it was not because they were seen as the main villains in the matter. Rather, it was because, from an administrative point of view, they were seen as the easiest to regulate.

In addition, it was believed that by regulating health care institutions, an impact could be made in other areas as well, areas not so susceptible to direct regulatory action, such as physician practices.

Now while "partnership" was the stated goal of the CHHC when it began in 1973, since 1976 when F. Bernard Forand became its executive director, the Commission has seen itself more as an "adversary" and less as an "associate" of the institutions it is overseeing. As a result, the period since 1976 has been one filled with conflicts between the hospitals and the Commission, conflicts which have been resolved in many cases only after the hospitals took their cases to the court.

In some of these cases, the issues centered around hospital budget requests which the CHHC refused to approve without first making substantial cuts. In other cases, the struggle was over a hospital's attempt to purchase a needed piece of medical technology for its patient, such as a CT scanner.

Some of these matters, such as a number of scanner applications, are still pending. Of the more than 30 cases that have been settled, however, more than 95 percent resulted in decisions in favor of the hospitals.

As hostile as the hospital regulatory environment in Connecticut has been in the past, the future could be worse, especially if the CHHC succeeds in having some of its most recent proposals enacted into law. During the General Assembly session this year, for example, it presented the legislators with a package that included the following measures:

1. **Extension of Commission Certificate-of-Need (CON) authority to non-hospital settings.** Issuing certificates-of-need is how the CHHC controls the purchase of medical equipment such as gamma cameras, CT scanners, laboratory computers, etc. by hospitals. With this measure, the CHHC was seeking to control the purchase of such equipment, by private groups of physicians, as well.
2. **Placement of the "burden of proof" for any CON application or budgetary item on the hospital**

VINCENT A. PROTA, Vice President, Planning and Regional Affairs, The Connecticut Hospital Association, Wallingford, CT. He was, prior to joining CHA in 1975, executive director of the Mid-State Connecticut River Estuary Comprehensive Health Planning Council, Inc.

rather than on the CHHC. Currently, the CHHC must explain its actions when it denies a hospital's request. This measure was designed to free the CHHC of that obligation, allowing the CHHC to simply say "no need (for the proposal) had been demonstrated."

3. **Extension of the CHHC's budget review period from 90 to 105 days for operating budgets and from 90 to 135 days for capital items.** Had the CHHC been successful in getting this measure enacted into law, hospitals would have had to put together their budgets for the next fiscal year based on only *five months* of actual data from the current year.

While the CHHC had no success this year in persuading legislators to enact its measures into law, there is no doubt it will try again in 1981, in many cases, with the same measures it supported this year.

Some of these proposals, it should also be noted, stem from the belief by some CHHC members that their function is similar to that of the Public Utilities Control Authority (PUCA) the full-time state agency whose job it is to review and act on rate increase requests made by the state's various utility companies. While not conceding that the CHHC's role should be limited to rate review, the CHHC members do suggest that their agency also should be a full-time body, paid for by funds assessed from the hospitals, in the same way the PUCA's activities are financed by the utilities they regulate.

This PUCA model unfortunately overlooks the fact that all of Connecticut's general hospitals are nonprofit institutions, unlike the utility companies which are profit-making. It is also hard to see how assessing hospitals for the cost of CHHC regulation could promote the cause of lowering health care costs in this state.

Up until now, hospitals have been able to rally their own resources to oppose many of the CHHC's most serious threats to their management prerogatives. To continue to succeed, however, hospitals will need not only their own resources, but those of all providers of health care, since it is the interest of all providers that is under attack. Only with such a united front will hospitals be able to continue to provide the quality of care of which the state has been so proud in the past.

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Of Mice and Men: What Animal Tests of Carcinogens Mean to Us

VINCENT T. DEVITA, JR., M.D. AND HARRIET PAGE KENNEDY

"What am I supposed to do about all these carcinogens?"

"What do animal studies mean for me?"

These are some of the questions physicians are hearing more and more, and many are at a loss as to how to answer them. What *does* it mean if a chemical is found to be carcinogenic in rats and mice? How realistically *can* we extrapolate doses and risks from animals to humans?

Answers to these questions are based on our current understanding of how cancer may be caused, and on how and why chemicals are tested for cancer-causing activity in animal experiments.

In terms of diagnosis and management, cancer is more than a hundred diseases, each one different, each with a different prognosis. But in terms of cause, there may be a very limited event or series of events at the cellular level common to all cancers.

High-dose or repeated low-dose radiation can begin this process, though we don't know yet exactly how. Viruses can trigger this growth in animals, though we are still seeking such a viral cause in humans. We know both from epidemiologic studies and from animal studies that exposure to some chemicals can begin the process. Finally, we believe that there may be a genetic factor present in some cases of cancer, a factor that may simply program cells to become cancerous at a given time, or one that may require the additional prod of a chemical, irradiation, or a virus.

The processes of initiation and promotion, for example, have been amply demonstrated in the laboratory. In this process a chemical initiator given to an animal does not by itself cause cancer. Subsequently, a promoter—which may by itself not cause cancer—given to the animal does cause cancer. There may, in addition, be other substances that act in concert, or act synergystically, to cause cancer; many natural occurrences have multifactorial causes.

One very fruitful line of inquiry, though, is to separate out just which chemicals in our environment—in our lifestyle, our workplace, our food, our water—are carcinogenic, because of the possibility that we can control our exposure to them. Considering the fact that tens of thousands of chemicals have been introduced into our society since World War II, and considering that new ones are being introduced into commercial use at the rate of about three a day, this is a herculean task.

Work in this direction has proceeded on a number of fronts. The International Agency for Research on Cancer, part of the World Health Organization, has for almost a decade been undertaking an exhaustive search of literature to assess and appraise reports of animal and epidemiologic studies. The National Institute for Occupational Safety and Health has compiled lists of substances at least suspected to be carcinogens. Ultimately, industry may be expected to test new chemicals before their introduction into the marketplace.

And the National Cancer Institute's Carcinogenesis Testing Program—now part of the new National Toxicology Program—has been conducting lifetime animal tests, or bioassays, with many hundreds of chemicals. The testing program initiated the Carcinogenesis Technical Report series with its first report, *Guidelines for Carcinogen Bioassay in Small Rodents.*

Since that report was published, 187 more reports on 227 chemicals have been published. Of these chemicals, 94 have been found to be carcinogenic in animals, and 83 of them have been found not to be carcinogenic to animals under the terms of the bioassay. (The remaining 50 chemicals were classified either as "sus-

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VINCENT T. DEVITA, JR., M.D., Director, National Cancer Institute and HARRIET PAGE KENNEDY, Office of Cancer Communications, Public Health Service, National Institutes of Health, Bethesda, MD.

pect" [18] or yielded inconclusive evidence [32].) Presently, there are approximately 203 chemicals on test.

Choice of Compounds for Test

In its early years, the testing program deliberately chose "suspect" compounds—pesticides and herbicides, for example—that could be expected to have carcinogenic activity. This deliberate choice explains in large part why so many chemicals tested to date have been shown to be carcinogenic in the bioassays. But the proportion of chemicals tested to those found to be carcinogenic should *not* be projected to all chemicals in our universe.

Later, chemicals were selected for test on the basis of their potential for widespread human exposure coupled with their structural "kinship" to chemicals already found to have carcinogenic activity. Currently, chemicals are selected chiefly on the basis of their potential for widespread human exposure and lack of sufficient data concerning safety or lack of safety.

Advice on which chemicals to test is received and considered from many sources, including regulatory agencies, industry, and academic scientists.

Test Animals

The animals used most often for bioassay in the testing program are the Fisher 344 rat and the B6C3FI mouse. Two different rodent species are used because rats and mice have demonstrated different responses to test chemicals. Hamsters are sometimes used, but they are short-lived and difficult to obtain free of infectious diseases. Larger animals, especially primates, become prohibitively expensive as test animals.

The Fisher 344 rat, an inbred strain, and the B6C3FI mouse, a hybrid, are both derived from pathogen-free colonies kept at the National Institutes of Health, and are brother-sister paired for a minimum of 20 generations. To maintain the purity of the stock, a new derivation is made from the NIH parent stock every 12 to 18 months. The animals are maintained in pathogen-free colonies throughout their lifetime.

The strict breeding measures accomplish a number of objectives. They assure that the animals will react to any test compound with the greatest homogeneity, the most genetically consistent response. Consistent use of these animals means that tests are readily reproducible. Most important, the natural cancer incidence in these animals has been extensively studied.

These rodents, like all animals, including humans, develop cancer in their lifetime. The incidence and location of these concers, "the background tumor incidence" as it is called, are well known and well documented. Against this background, the appearance of different types of tumors in different sites, or a greater than normal number of tumors, can be determined.

Routes of Administration

When feasible and practical, test chemicals are administered to the animals by routes that simulate human exposure. Gases are administered by inhalations, for example, and substances ingested orally are given in the feed, the water, or by gavage. Gavage is often used if the chemical is not stable in food or water; sometimes it is used if the chemical is distasteful to the animal. If the test chemical is a drug, it may be administered by injection. The important aspect of chemical administration is that it be delivered to the animal systemically so that its full impact on all organs and tissues can be assessed.

Doses

Animals are deliberately administered the largest dose of a test chemical that they can tolerate without life-threatening toxicity. (This is often far higher than the doses used in standard toxicity tests.) This high dose, ascertained in preliminary tests of weeks or months, is designated as the maximum tolerated dose, or MTD. It is administered for two reasons:

1. It offers the greatest assurance that carcinogenic effects, if indeed the substance is carcinogenic, will be expressed during the lifetime of the necessarily small numbers of animals used in each test.
2. If carcinogenic chemicals were given in "realistic" doses—that is, doses comparable to levels of possible human exposure—many thousands of animals would be needed in order to observe tumors in significant numbers of them. High doses will produce effects in smaller numbers of animals. This concept is referred to as "the power of the test."

In a typical bioassay, groups of 50 rats and 50 mice of each sex are given the MTD and other groups of 50 each serve as controls. A test using these relatively small numbers of animals, which are given the chemical for their life span, now costs about $500,000. For each additional group administered a lower dose, there would be concomitant increases in cost.

Lifetime Dosage

There is a latency period between exposure to a carcinogenic substance and the development of cancer in man or in laboratory animals. For some known human carcinogens, the latency period may range from 20 to 40 years. But because the latency period of a test chemical, if it is a carcinogen, is not known, it is believed that continued administration of the substance for the animal's lifetime presents the greatest opportunity for cancer to develop.

Under the two conditions described above—maximum dose and lifetime administration—the test chemical is thus given the greatest opportunity to express its potential cancer-causing effects if it possesses any. Under these conditions, a negative result then reflects at least some assurance that the test chemical is not a carcinogen.

How Can We Extrapolate Animal Results to Man?

As matters stand, there is no mathematically valid way to state that if dose *x* of a carcinogen causes cancer in mice, then dose *y* will cause cancer in humans. The problem of risk assessment is just beginning to be addressed by a number of government agencies in a meaningful way.

We can say that an agent found to be carcinogenic in animals must be regarded as a probable human carcinogen. We are on very firm ground for this assertion. We must remember that mice and rats are not "little people." However, they are viable mammalian cell systems, and we do know that mammals behave in comparable ways, including responses to environmental insults. We know, for example, that 26 of the substances known from epidemiologic studies to be human carcinogens are carcinogenic in animals. In fact, six of these substances, DES (diethylstilbestrol) among them, were found to be animal carcinogens before they were discovered to be human carcinogens.

Individual responses to carcinogens, to drugs and to many substances are extremely variable. Even in our inbred rats and mice, for example, tumors of the same type rarely develop in all of the animals in a particular test. And we humans are generally very heterogeneous compared with the very homogeneous animals we study. As Barry Commoner has said, "Sometimes we humans behave like rats, sometimes like hamsters, but most of the time some place in between."

We humans also are exposed to many different substances in our lifetime. Perhaps we are exposed to many carcinogens over a period of time. Perhaps we are exposed to substances that have a protective effect. Perhaps genetically, some of us have better reparative mechanisms than do others. We don't know, in short, what the threshold, or "no-effect" dose of any chemical is for any given individual, or even if there is one. So we must assume for the sake of caution that there is no threshold or safe dose of a carcinogen.

How, then, are we to treat a substance that has been determined to be a carcinogen: Will our society demand nil exposures? This seems highly unlikely. Will it work out permissible exposure levels? This seems more likely. These are very complex problems that will take many years to solve.

The Delaney Amendment requires the Food and Drug Administration to ban food additives that are demonstrated carcinogens. In the case of saccharin, though, even such a clear mandate ran into obstacles because of the conviction of many that saccharin is not "very" carcinogenic. In other words, our society seems to be demanding that we not only ascertain whether a substance is carcinogenic but also "how" carcinogenic.

The mandates of the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Toxic Substances Control Act, and the Environmental Protection Agency are even less clear-cut than that of the FDA. Some hint of the difficulties that face us can be seen in the recent Supreme Court decision regarding benzene exposure for workers.

Benzene, a widely used industrial solvent, is a known carcinogen. OSHA's ruling that permissible exposure limits in the air be reduced on job sites from 10 parts per million to one part was struck down by the Supreme Court on the grounds that OSHA had failed to demonstrate either the risks of the higher exposure or the benefits of the lower exposure.

These are two examples, therefore, of our society's unwillingness to legislate nil exposures. The job remains, then, to work out risk/benefit ratios based on a better understanding of just how dangerous dangerous substances are.

Better Studies Coming?

The animal studies now in use are the best that anyone has devised, but they are expensive and time-consuming. There is now some hope that the present bioassay program may be augmented or one day even supplanted by batteries of *in vitro* tests. These tests—for mammalian cell transformation, for gene induction, for chromosomal abnormalities at the cellular level, or for mutations (such as the Ames test)—may only take weeks or months and cost only a few thousand dollars.

As yet, no single test or single battery of in vitro tests has emerged as the best suited for carcinogen testing or carcinogen screening. Nearly all of the tests produce both false negative and false positive results. (The Ames test, for example, was positive for Tris, the flame retardant, but negative for DES.) Two large-scale studies, one an international effort involving some 60 scientists in a number of countries, the other one being conducted by the NCI under the auspices of the National Toxicology Program, are now under way. From these studies it is hoped that batteries of in vitro tests using cell systems will emerge as a better, faster and cheaper way to screen chemicals for carcinogenicity.

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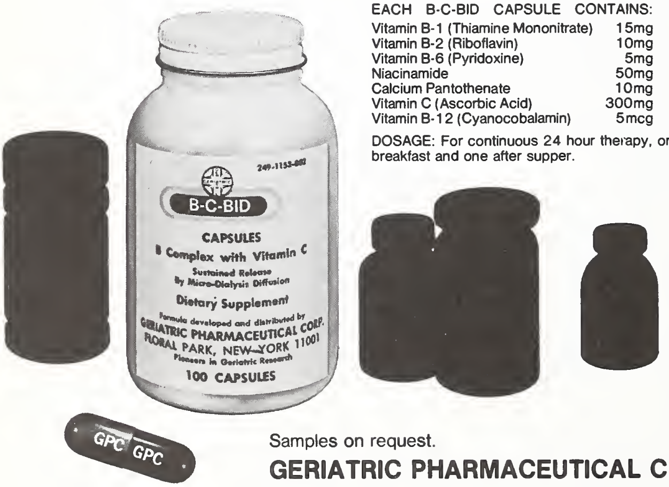
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An Infant Apnea Center for the State of Connecticut

BERNARD P. SCHACHTEL, M.D.

One of the more challenging problems confronting a physician is apnea in an infant. Is the reported episode of "not breathing" a transitory phenomenon such as brief inco-ordination of swallowing or breathing? Is it a sign of a chronic disorder, such as seizure? Is it the sign of recurrent apnea, possibly resulting in crib death? The diagnostic and prognostic dilemma is profound.

This summary cannot answer these questions for each case. Rather, the purpose of this article is to present our current understanding and management of apnea; to relate the clinical investigation of apnea to that of S.I.D.S. (Sudden Infant Death Syndrome); and to describe the Connecticut-based program founded to serve families with infants at risk for recurrent apnea.

Apnea

All humans, infant and adult, have periods of not breathing. Of short duration, as after a sigh, an apneic episode is of no pathologic significance. However, when apnea lasts longer than twenty seconds, it is considered abnormal. The clinical consequences of this prolonged apnea are certainly significant when the infant is observed by a parent to be blue, dusky, or pale, limp and unresponsive, requiring vigorous stimulation or mouth-to-mouth resuscitation to restore respiration.

Such an episode requires immediate medical evaluation. If any central nervous system sign is detected soon after the episode, it may indicate a seizure disorder; it is also an index to the duration and severity of hypoxemia. Usually, however, the physical examination reveals a normal infant. Diagnostic tests may be obtained in the emergency room, as indicated by the history and examination. The most important diagnostic and therapeutic intervention, however, is continuous respiratory and cardiac monitoring during the in-hospital evaluation. Key to this process is the sleep pneumogram, a 12-hour recording of respirations and cardiac impulse, often helpful in documenting a specific cardiorespiratory abnormality, such as prolonged apnea, periodic breathing, or bradycardia. While central apnea[1] may be the diagnosis, other possible etiologies include infection, gastroesophageal reflux, seizure disorder, anemia, anatomic obstruction. As in other areas of medicine, correct diagnosis is critical to appropriate therapy.

Clinical Investigation

Over the past decade, research about apnea has produced findings which have expanded our knowledge about S.I.D.S. In early studies of apneic infants, a significant proportion of the patients subsequently died of crib death.[2,3] Follow-up studies on other apneic infants have suggested other serious consequences of hypoxia, such as cerebral palsy and mental retardation. Other studies on these "near-miss" S.I.D.S. patients have documented evidence for hypoventilation, a higher-than-normal resting alveolar pCO_2 and a blunted tidal volume response to increased ambient carbon dioxide.[4]

An argument for chronic hypoxemia due to intermittent hypoventilation thus has been developed in some of the apnea studies. A corollary to these findings has been developed in the research on S.I.D.S. victims. Of the autopsies studied, most revealed pathologic markers for chronic hypoxemia, such as hypertrophied pulmonary arterial and right ventricular muscle mass, increased periadrenal brown fat, and extramedullary hematopoiesis.[5-8] From these studies, it is clear that many infants who succumb to S.I.D.S. are not well before they die. Regretfully, our tools for detecting these abnormalities before they first present clinically are not sufficiently fine. Of particular note in this regard are studies on the siblings of S.I.D.S. victims. In these siblings, who have a statistically increased risk of S.I.D.S., pneumograms that reveal abnormalities such as a high percentage of periodic breathing can be used to help determine those siblings truly at risk for S.I.D.S.

BERNARD P. SCHACHTEL, M.D., Assistant Clinical Professor of Pediatrics, Yale University School of Medicine.
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The Infant Apnea Center

S.I.D.S. is the leading cause of death in infancy, responsible for 1-2 deaths per 1,000 live births and second only to accidents among all causes of death in childhood. In Connecticut, for example, S.I.D.S. claims approximately 40 lives each year. Because of this impressive rate and because research has indicated a probable relationship between some cases of apnea and S.I.D.S., the Infant Apnea Center was created to provide a local, comprehensive program for apneic infants in Connecticut.

Under the auspices of the Connecticut Junior Women, Inc. and the Fairfield County-New Haven Chapter of the National S.I.D.S. Foundation, the Center has been designed to provide medical, nursing, technical, and social services. Diagnostic evaluation is available for any infant referred by a physician who considers the infant at risk for recurrent apnea. Infants with a history of apnea, siblings of S.I.D.S. or apnea victims, and premature infants with apnea or bradycardia comprise the major categories or referrals. The Center also provides diagnostic consultation to physicians for patients with medical diagnoses that include apnea, such as intractable seizure disorders, enlarged tonsils, gastroesophageal reflux.

The medical evaluation usually lasts three days in the home-decorated room (with sleeping facilities for parents and infant) while tests such as a sleep pneumogram and continuous cardiac and respiratory monitoring are performed. The Medical Director conducts this evaluation and, working with the referring physician, provides subsequent medical care for the infant's apnea. The Nurse Co-Ordinator conducts the educational program about apnea, monitoring, and cardiopulmonary resuscitation, and the Center's Social Worker has responsibility for counselling parents how to cope with adjustments in daily living. Our 24-hour availability to parents is complemented by the same availability of a monitor technician and, if needed, a "back-up" monitor always in the Center. Home visits, telephone calls, written reports, and office appointments are vital components to this on-going communication, as are the monthly Monitor Parents' Group meetings and bi-monthly newsletter, the *Parent Cable.*

Finally, the Center has been planned to act as an educational service. Lectures are offered to health professionals and the public to help answer the ever-present questions concerning apnea and S.I.D.S.

To date, the Center has evaluated over fifty infants referred from all corners of Connecticut. The program has proved itself to be available and useful to each community in the state. For this is the overall objective of the Connecticut Junior Women who sponsor the Center—to serve all families in the State of Connecticut.

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The Problem of Physician Impairment

JOHN-HENRY PFIFFERLING, PH.D.

Introduction

The medical profession has become intensely concerned with the problem of the impaired physician. As with diseases or conditions which do not have a single cause, there are multiple suggestions as to the origin, contributive factors and types of susceptible hosts.

It is therefore urgent that the overall problem, its component parts and the numbers of affected physicians be defined. These epidemiologic factors must be established if we are to develop successful prevention programs.

The following analysis of available, limited information will indicate both the nature of the dilemma and why potential remedies and preventive measures may be so difficult to apply.

The Problem

The American Medical Association defines the impaired physician as "one who is unable to practice medicine with reasonable skill and safety to patients because of physical or mental illness, including deterioration through the aging process or loss of motor skill, or excessive use or abuse of drugs including alcohol."[1] The AMA also conservatively estimates that one of every ten physicians is thus impaired. Impaired or disabled doctors deny their disablement, persist in their professional activities, and are generally unable to seek help spontaneously.[2]

Physicians, like other humans, suffer from the vagaries of life and become impaired, but their cultural values deny them the opportunity for professional and personal support. American culture imposes tremendous expectations upon physicians, who often are unable to resolve the needs of their own personal lives with the idolized service expected of them.

Scope of the Problem

Physician impairment is a study in extremes. Traditionally considered smarter, more dedicated, and harder working than their peers in other occupations, physicians also run a higher risk of developing serious disabilities. Painfully aware of their mission to serve mankind as healers, physicians paradoxically neglect their own well-being, at great cost to themselves, their families, and their patients.

Physicians are too harried and too busy to lead healthy lives. They are overburdened by perfectionistic, mythologized self-images.[3] In at least two documented areas, they are slow in seeking treatment for themselves—when they have cancer or psychiatric illness.[3]

Physicians pay more attention to their patients' treatments than they do their own.[4] Seventy percent of physicians in one study did not get regular checkups.[5]

But as patients, physicians are overdiagnosed and their surgical use rate is three times that of the general U.S. male population.[6] It is probably fair to state that as a special population, physicians and physicians' families as patients are less well understood than most other groups. For example, alcoholic physicians generally refuse or ignore timely treatment. Also, once physician alcoholics have begun treatment, they are often treated for illnesses other than their primary problem, alcoholism.[7] Physician patients, especially alcohol and drug abusers, routinely leave treatment centers against medical advice and before the completion of their treatment.

Almost all studies on physician impairment concentrate on retrospective accounts of physicians' emotional health biasing epidemiologic baselines. Our review is thus subject to incomplete data derived from researchers who are psychologically minded. A sense of urgency surrounding the emotionally impaired physician research exists given the inference that improper patient care is more likely to ensue from their activities than from those suffering from "physical" diseases.

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Emotional impairment may remain a high risk for physicians if medical training values continue to place a premium on overburden.

The underlying philosophy behind most medical training programs is that trainees should overwork, and if a trainee cannot take the stress then s/he should "get out of the kitchen." The trainees themselves have unrealistic expectations for their performance which predispose them to anxiety. Many trainees are also unaware that the increased stress of clinical training places them at an increased risk for cumulative effects of improper coping and probable, subsequent emotional impairment.[8]

Core practice habits and behavioral patterns are engraved most deeply during residency. Yet residency training environments generally neglect the personal development of the physician and fail to offer assistance during the coping dilemmas of the resident.

The psychological states of interns and residents have rarely been studied, though most autobiographical descriptions by residents indicate that they are prone to psychological dysfunction. Valko and Clayton (1975) found that 30 percent of 53 residents in medicine, pediatrics, and surgery had had depression during the internship.[9] Seven had suicidal ideas, and six with no previous marital difficulty had marital problems. The medical, social, and childhood histories of the depressed and nondepressed groups were not significantly different. The majority of the interns were working more than 100 hours a week when their depressions began. None had a significantly stressful event in the month prior to the onset of depression. Confirmatory evidence on residents is also available from a recent survey by the American Academy of Family Practice (1979). This group found that among 233 programs responding, 70 percent had identified impairment in specific residents.

Compared with their social peers, physicians are twice as likely to misuse psychoactive drugs.[10] Yet even these estimates are considered to underestimate the problem.[11] In cases in which reliable psychiatric data are available, depression was found to be the underlying cause of drug abuse. (Ready access to drugs is still an incompletely understood variable in the physician drug abuse rate.) Almost all studies on physician addicts found a pattern of progressive deterioration of the personality with depression, hypochondriasis, inability to withstand stress, and development of conflicts associated with the physician role ("role strain"). Reported physician addicts tend to be diagnosed about age 45 when "success" should be most assured.[12] They are rarely reported by colleagues. Often, major stresses such as chronic illnesses, family tragedies, and apparent poor coping to practice pressures are implicated as causing the addiction.

There is much confusion among researchers in alcoholism as to the extent of alcoholism among physicians. Numerical estimates range from the AMA's figure of 17,000 (disabled by alcoholism and drug dependency - 1975) to Green, Carrol and Buxton's report of approximately 25,000 (1978).

In retrospective accounts of physicians admitted for psychiatric treatment, alcoholism is not the most frequent diagnosis.[13] Alcoholic physicians rarely seek help and when admitted for psychiatric care are usually not given primary diagnoses of alcoholism. National alcoholism probability statistics suggest that there should be 500 to 600 cases among Virginia physicians alone yet only two or three cases are brought to the Virginia State Board of Medical Examiners in any year.[14]

Physicians take their own lives with greater frequency and generally at an earlier age than members of the general population. Suicides account for about 28% of physician deaths before the age of 40 compared with 9% for all white males of the same age group. Suicide rates for women physicians are the highest reported for any occupational group of women. They are nearly four times those of the general population of women who are more than 25 years of age.[15]

The correlates of male physician suicide usually include a sense of hopelessness associated with the practice, depression, drug dependency, chronic disease, and failure to cope with the loss of the practicing physician role (through retirement), and professional success but personal failure (via alienation from spouse or children). Female physician suicides tend to occur during residency. One explanation for this age and sex difference could be that some vulnerable females react to an enforced masculinization during medical training with an overpowering sense of loss of their womanliness. Depression and suicide then ensue.

In retrospective, psychiatric accounts of completed physician suicides, the conduct of a disabled doctor's practice reveals a pattern of precursors common to suicide. Included in this composite account are a hurried existence, self-doubts about ordinary medical procedures, marked indecisiveness when confronted with difficult diagnostic problems, and gradual practice neglect.[16] These physicians often leave regular colleague contacts, retreating from a hospital association to a solitary office practice. Questioned later, colleagues of the suicided doctor recall having observed indecisiveness, disorganization, and depression. But they have rarely confronted the suicidal doctor and harbor nagging feelings of guilt.

Aggravating Factors

Premedical Education

Premedical students quickly learn that they must be achievement oriented and acquire an outstanding scholastic record. Competition for grades becomes a way of life among premedical students, who allocate time for studying first and for other life-maturing experiences last. Their social experiences are generally limited, often restricted by guilt feelings that someone else is studying and will get the coveted place. Later nightmares such as intense fear of failure are preshadowed in the premedical program. All in all, presocializing experiences as a "premed" prime the students' egos for overachievement and the limited rewards of the workaholic pattern.

Medical and Residency Education

Traits that help earn entry to medical training—such as self-sacrifice, perseverance, competitiveness, and denial of personal feelings—are magnified by the typical medical school experience, an experience that allegorizes devotion to work and the internalization of the work role as the trainee's self-image. For example, in their first clinical rotations, medical students joust with each other as to who had the least sleep or the most "workups." The denial of weakness is a first lesson that homogenizes most medical education; its pervasive existence shapes the affective conditions that later cause colleagues to conspire in silence when a physician is troubled or vulnerable. Dealing with serious issues such as helplessness, and hopelessness, exposes students to constant emotional challenges. They respond by feeling fear, anxiety, insecurity, and frustration. Often these emotions are combined into a single, encompassing term: dread.

Medical students leave the premedical environment feeling ecstatic at their success with medical school admission. They have set a difficult goal, maintained a hard pace, and can congratulate themselves on their discipline, and single-minded purpose. When they enter medical school they suddenly confront their subordinate status. Their hope for independence conflicts immediately with their dependence on faculty for positive strokes, on patients for ego gratification ("you cured me"), on peers for social support, and on nurses for learning routine procedures.

Only gradually do they begin to feel more comfortable as doctors (since in the first two years they are mostly taught by nonphysicians); then they enter internship where they are often unable to cope with the greater and different stresses encountered. Both medical students and housestaff are debilitated by social and sleep deprivation; by test or board anxiety; by mistake fantasies; and by their seemingly eternal student status. Thus dread, dependency, and debilitation describe part of the process of becoming a physician in most American medical schools.

In many medical school environments a system of reinforcement fosters the development and exaggeration of traits and behavioral patterns that may later become debilitating, e.g., a tendency to develop an excessive work load, self-denial, repression of feelings, inattention to personal needs, and intellectualization of emotions. Medical school is hard, which we may not want to change, but do we want the driving hardness to damage our doctors for life?

The detached hardness of medical training facilitates an attitude towards the use of mental health services, and the mental health professions, that compounds the treatment of physicians when they do request it. When they use services for themselves, their treatment is often inadequate because physician-patients need to maintain facades of adequacy and control. Their therapists, likewise, often have difficulty in managing physician patients because they identify with them, and use defensive denial to conclude that both are more well than ill.

Medical training also fosters an attitude that idealizes technical and scientific management, perhaps to the detriment of the clinical, human encounter between doctor and patient. Academic medical centers uniformly favor the scientific experience over the clinical; the specialist over the generalist; the bench researcher over the clinical teacher; the completeness of the "workup" over the most patient-beneficial. It may be that these values predispose trainees to become technologically astute but clinically rigid.

Attitudes of technical mastery and omnipotence over the ambiguous subject area of the human condition predispose the physician for predictable feelings of dread that he cannot master. Physicians are constantly involved in transference feelings, being in one minute the resident-learner and in the next resident-physician. Physicians must simultaneously learn to protect themselves from their patients who tantalize with ego rewards and dependency needs in a circadian rhythm that would fatigue even that superhuman of popular myth, the young American physician. Supported by public and medical media manipulation of this greater-than-life image, the faculty, trainee, and the public lose sight of everyday limits upon the physician, who, all are convinced, deals in everyday miracles.

The paradoxical aspects of medical training extend from training programs to physician habits. For example, medical trainees cope with patient illness in tertiary care hospitals, and are taught by tertiary care faculty, but only five percent of these young physicians will ever go into academic medicine. Both the diseases they encounter and the technology and medical resources at hand in training differ widely from the everyday problems they must attempt to resolve without resources when they are in practice. The conflict between their expectations and the reality of practice mirrors the initial discomfort they felt when they euphorically entered medical school only to learn that humanistic, clinical practice is an ideal unattainable to most. The separate, perfectionistic demands of the technological training world, ever increasing "necessary" information, and their patients' and their own image of the physician produce an accommodation that allows no opportunity for synthesis.

Socialization for physicianhood discloses two especially salient themes for young physicians: a recurring confusion between personal identity and career identity; exaggerated competition between time for work and time for self and independence that are often expressed as a fear of acknowledging any need for care.[17] Coombs notes, "The subjective features of medical education, if discussed at all, are usually covered on an intellectual level. So unless students have informal channels to 'unload' personal feelings are routinely suppressed. Because of this . . . some clinicians are needlessly hampered in their ability to provide healing aid . . . . "How can a doctor allay the fears and anxieties of others if his or her own feelings have never been resolved?" (1978:252)[18]

Partly because so many expectations are placed on the medical educator, the medical trainee, and the academic medical setting, a clearly shared vision of the end product does not exist. Though most medical schools state their goal as teaching physicians to care for the whole person, they fail to recognize that medical students and housestaff are no less whole people than are the patients, and most often deal with them only in terms of their professional roles. The personal development of providers, including the acquisition of personally destructive habits during and subsequent to training, is viewed by most medical educators as irrelevant to their professional functioning.

Societal Factors

American medicine is at once a mirror for American society and an example of the work ethic carried to extremes. Physicians are socialized in an occupation that promises technological solutions to problems on a level that cannot be solved solely by technological interventions. Both consumers of medical services and providers expect the latest available technology and that the providers are competent in its use. But the bulk of problems that are present in ambulatory contexts require nontechnical interventions. Physicians worry about the potential errors associated with more and more complex technologically derived data and spend less time worrying about the quality of their clinically derived data.[19] Time spent coordinating, managing and interpreting biomedical data ruthlessly becomes symbolic of working as a physician. On the other hand patients expect physicians to be freer to spend time with them—not the obverse as in a study where physicians physically spend, on the average, less than a minute with each of their patients.[20] Working hard in an ever expanding biotechnical world means more interprofessional communication for the physician and less time reaping the rewards of the healing bond.

Society demands a medicalized (with health as the ultimate value) worldview, finds willing servants in physicians fueled by a medicalized educational system, and then decries the transformed transaction. Physicians, usually unaware, become technocrats; sick people become disease entities; and the healing bond becomes a commodity transaction constrained by bureaucratic algorithms.

Prevention

Our approach to the problem must then necessarily be two-fold. First, we must move beyond the acknowledgement to confrontation of the problem. We need in our second step to focus on methods of prevention, early correction, and modification of the population-at-risk.

If personality and family background factors are partially etiologic in impairment problems among physicians, we can screen out or modify the population-at-risk. Screening out assumes that individuals with given risk factors will necessarily develop the at-risk problems, and that tests measuring these risks are valid and specific. Both assumptions can be faulted.

Modifying the population-at-risk entails the use of coping models of training, such as values clarification, support group experiences, and stress management techniques. Many of these models have been validated and several of them are now being added to programs that stress interpersonal skill training. Some programs combine several models and apply them to both medical trainees and faculty. The goal of such attempts is to set feedback loops in motion. Currently a variant of this model is offered at the University of Connecticut Medical School were counseling and support group services are offered to all medical and dental students.

In the wider context of medical education, the most difficult factors to change relate to the common training model that relies on memorization, overwork, and audit by default.

Medical education stands today as one of the few academic fields wedded to a paradigm based on memory.[21] Students and residents cannot integrate fast-changing information if they continue to rely on feats of memory roundsmanship. Nor can they build their bases of information if their faculty deny them an opportunity to routinely perceive the logic behind clinical decision-making. Computerized medical information systems coupled with clinical documents that attempted to preserve the logic of decision-making could help topple the tyranny of memory that guides medical education. In the medical setting, coordination is acknowledged as necessary to patient treatment; but often avoided as unpleasant housekeeping. By entrusting a single health record to a single patient, permanently cared for by the patient as record librarian, coordination could be facilitated.

If greater participation by patients in medical decision-making will bring them to accept some of the responsibility now borne by the physician, the physician can continue to have authority but in a more limited sphere. Patient responsibility will place control where it legitimately belongs. Patients live with the variables all the time. If they are aware of these variables as risk-enhancing factors, they can initiate coordinated care plans better than anyone else. Physicians only see a fragment of the total during a fragment of the patient's life. Why demand responsibility from the physician for comprehensive care when s/he can never know or control most of the variables?

If patients and society take and share responsibility, then dependency states (which lead to inefficient utilization of the medical care system) are not reinforced, and the interactions between the patient and the physician can celebrate each other's dignity, autonomy, and self-worth.

Conclusions

If we fail to confront the variety and consequences of physician impairment, we will allow needless disablement to continue. We may also be contributing to the declining public trust in physicians. We must confront the conspiracy of silence that surrounds a troubled physician and his family. We must confront the fear of betrayal to self and to the profession when one wishes to aid the impaired physician. We must openly admit the fear of contagion if one truly hears, listens, and responds to a request for nurturance and involvement from a troubled physician. We must remember that physicians are individuals first and health care workers second.

Steps Towards a Solution

In order to prevent physician impairment, several efforts must be made. A model for the physician role must be developed that allows many options for the medical graduate. This could include practitioners that practice augmentative medicine: health oriented and not disease centered. The risks of emotional disability associated with medical training must be publicized. Concern for the well-being of medical trainees must be continuously modeled in medical training. Rituals of education must be purged so that training is efficient and emotionally rewarding. Students must be rewarded for displaying behavioral patterns that characterize efficient problem-solvers not memorizers. Clinical skills including interpersonal affect must be monitored, emphasized, and rewarded. Prestige must accrue from many avenues but especially from positive medical outcomes. Physicians that share responsibility with colleagues and patients should be granted both professional and societal status. A new-age physician can and must be trained so that needless human wastage is reduced.

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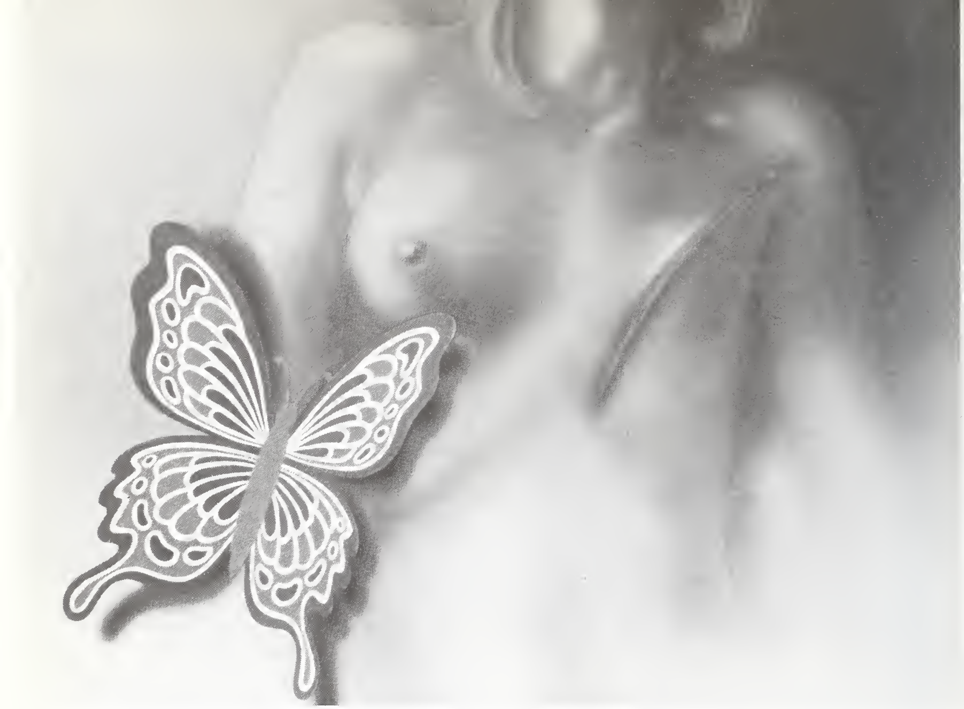

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Physician Competence

AMA COUNCIL ON MEDICAL EDUCATION

The House of Delegates, during the 1977 Interim Session, adopted Report E of the Council on Medical Education with the following recommendation:

> "That an Ad Hoc Committee of the Council on Medical Education be formed to study this matter intensively. This Committee should serve as a coordinating influence, bringing together the many fragmented approaches, and finally guiding the profession to establish the best method in which to document the continuing competence of the practicing physician."

The most satisfactory and complete definition of physician competence that the Council and its ad hoc committee have seen is contained in the report of the Committee on Continuing Competence of Physicians of the Coordinating Council on Medical Education (CCME), which, after four years of study, was submitted to the CCME in June 1978:

> "*Physician competence* is the function of an array of attributes which compose a pattern of effective activity directed toward the health care and wellbeing of people as individuals or as groups. Three essential dimensions are usually recognized and encompassed:
>
> "A. *Knowledge:* Factual knowledge and understanding relating to the function which the physician is called upon to perform.
>
> "B. *Abilities* which include:
> 1. Communication skills
> 2. Technical skills
> 3. Self-discipline and work habits
> 4. Professional attitudes
>
> "C. *Clinical judgment:* The capacity to apply the appropriate knowledge and skills at the right time. Included in this is the synthesis of hypotheses from the data and the appropriate testing of those hypotheses."

Any attempt to assess physician competence, therefore, must measure those three components: knowledge, technical abilities, and clinical judgment. These basic elements of physician competence may be measured by a variety of tests and instruments, of which the most commonly mentioned are listed below:

Measurement of knowlegde or understanding:
1. Objective tests (free response and ten types of limited response)
2. Essay tests

Measurement of abilities:
1. Communication skills
2. Technical skills
3. Self-discipline
4. Professional aptitudes

Measurement of clinical judgement:
1. Simulation techniques (Patient Management Problems)
2. Computer-based simulations
3. Medical audit techniques

It is abundantly clear that a complete definition of physician competence, by recognizing the many facets and multiple complexities involved, *excludes establishing any single or best method for developing or measuring competence.* The present state of the art does not permit the measurement of all of these elements in a practical manner for large numbers of physicians nor at a reasonable cost. If such elaborate evaluations were implemented, the cost undoubtedly would be reflected in increased costs of health care and extensive loss of physicians' time from patient care.

All who have given this subject serious consideration agree that *the assessment of physician competence by any one national organization or agency, including the federal government, is virtually an impossibility to perform.* The logistics and expense involved would be astronomical in relation to the comparatively few incompetent physicians that might be discovered. It is common knowledge, as a result of the functioning of medical staffs of hospitals under the audit and review requirements of JCAH and the medical care evaluation

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EDITOR'S NOTE: This is a report of the AMA Council on Medical Education to the House of Delegates at its Annual Meeting in July, 1979.

studies required under PRSO, that both quality of care and individual physician performance best can be evaluated by the peer group at the local level. Advances in technology now permit an ever-increasing number of hospitals to demonstrate that computerized records and analysis of practice patterns, as well as professional surveillance over physicians' competence by the hospital staff, is more reliable, efficient, and cost effective than any state, regional, or national system.

Much emphasis has been placed on continuing medical education as a mechansim for assuring continuing physician competence, but there is currently no assurance that this continuing medical education to which the physician was exposed was what he needed, or that he learned correctly what he was taught, or, indeed, that he later applied what he had learned to apply in his practice. There is absolutely no question that continuing medical education is a valuable component in the array of elements necessary to the maintenance of competence, but it is only one such component. Consequently, the accumulation of CME credit hours is not an adequate or an accurate testimony of competence, and therefore, at best, is an unsatisfactory basis for re-registration of the license.

Despite the inappropriate use of continuing medical education for this purpose, 24 states now have legislation requiring some form of continuing medical education as a basis for re-registration of the license to practice; however, not all of the legislation has been implemented to date.

Similarly, there has been a strong movement toward accepting specialty board certification and recertification as evidence of continuing competence to be used toward requirements for relicensure. All of the 22 specialty boards have policies providing for recertification; 16 boards have fixed dates on which recertification processes will begin. Some boards are actively reconsidering their positions and two have reversed their earlier decisions on dates to begin the process.

Specialty board certification (and recertification) has the purpose of recognizing excellence in qualifications and standards of practice and should remain voluntary. Licensure, on the other hand, recognizes only those who have passed the minimum standard of qualification for practice and must remain mandatory. To use specialty board recertification, therefore, as evidence of having exceeded the minimum standards required for re-registration of the license, would seem to be not only inappropriate, but also a depreciation of the value of recertification. If the profession itself equates specialty board certification and recertification with competence, the public cannot be blamed for regarding the uncertified physician as lacking competence. The implications of that assumption should be apparent to all physicians.

Although the Federation of State Medical Boards has repeatedly urged acceptance of recertification for re-registration of licensure, at present there are only nine states (Arizona, Colorado, Massachusetts, Minnesota, Michigan [partial credit granted], Maryland, New Hampshire, New Mexico, Utah, and Washington) which will re-register the license to practice medicine on the basis of specialty board recertification.

If recertification is adopted more widely as the basis for licensure or license re-registration, then probably the only way to assess the competence of uncertified physicians engaged solely in office practice would be by mandatory requirements (such as examination based on practice profiles) imposed by the state licensing boards for re-registration of licensure. The interval between these imposed requirements is not yet clearly indicated for the uncertified physicians. There is no uniformity of intervals between proposed recertification by the various specialty boards.

A report on physician competence must also address the issue of incompetence. The vast majority of physicians are conscientious about keeping abreast of new developments and maintaining their competence. To identify and remove from practice the few incompetent physicians is much easier than forcing all other doctors who are competent to prove their competence periodically by means of the elaborate, expensive, and time-consuming evaluation procedures now underway or being planned. Also, it is much easier and less expensive to identify the physicians who are incompetent, because of outdated knowledge and skills, and to employ existing programs or methods to correct their deficiencies. Of course, it is recognized that efforts to identify the incompetent physician by periodic evaluations may improve the competence of other physicians, but it is not an efficient or cost-effective method. Continuing medical education alone at the present time is a $2 billion annual business; a large portion of these costs is undoubtedly reflected in the higher cost of health care.

There are laws which protect both the complainant and the state boards from prosecution in cases where a physician reports another physician whose capabilities are impaired or whose practices are incompetent.

The Council recommends that the AMA urge:

1. The members of the profession of medicine to discover and rehabilitate if possible, or to exclude if necessary, the physician whose practices are incompetent.
2. All physicians to fulfill their responsibility to the public and to their profession by reporting to the appropriate authority those physicians who, by being impaired, need help, or whose practices are incompetent.
3. The appropriate committees or boards of the medical staffs of hospitals which have the responsibility to do so, to restrict or remove the privileges of physicians whose practices are known to be incompetent, or whose capabilities

are impaired, and to restore such physicians to limited or full privileges as appropriate when corrective or rehabilitative measures have been successful.

4. State governments to provide to their state medical licensing boards resources adequate to the proper discharges of their responsibilities and duties in the recognition and maintenance of competent practitioners of medicine.
5. State medical licensing boards to discipline physicians whose practices have been found to be incompetent.
6. State medical licensing boards to report all disciplinary actions promptly to the Federation of State Medical Boards and to the AMA Physician Masterfile. (Failure to do so simply allows the incompetent or impaired physician to migrate to another state, even after disciplinary action has been taken against him, and to continue to practice in a different jurisdiction but with the same hazards to the public.)
7. The American Board of Medical Specialties and its constituent boards to reconsider their positions regarding recertification as a mandatory requirement (which has been equated with minimum qualifications for medical practice already in nine states) rather than as a voluntarily sought and achieved validation of excellence.
8. The Federation of State Medical Boards and its constituent state boards to reconsider and reserve their position urging and accepting specialty board certification as evidence of continuing competence for the purpose of re-registration of licensure.
9. The Federation of State Medical Boards and its constituent state boards reconsider and reverse their position urging and accepting continuing medical education credits as evidence of continuing competence for the purpose of re-registration of licensure.

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Month in Washington

A provision barring freedom of institutional choice for Medicaid patients has provoked the strong opposition of the American Medical Association.

Approved by the Senate Finance Committee as part of a budget cutting package, the controversial provision would repeal the present right of Medicaid patients to exercise free choice in selecting qualified suppliers of medical services. The amendment authorizes states to limit access to care to certain hospitals and other providers.

Although the provision would set an important precedent involving freedom of choice and raises again the question of a two-tier health system, it was scarcely noticed by the public press in the hectic scrambling of a Congress that wishes to be elsewhere than Washington in this election year.

In a letter to committee Chairman Russell Long (D-LA), the AMA said the provision "would change the entire thrust and philosophic basis for the Medicaid program. Rather than continuing the program as designed, to provide access to mainstream medical care for the poor, it would authorize a two-tiered system of providing care—one for the general public and another for the poor."

James H. Sammons, M.D., AMA Executive Vice President, said this major redirection of the program is highly undesirable.

Dr. Sammons called for public hearings and opportunity for consideration by the public and the committee. "We deplore such precipitous action that would have the long-term effect of institutionalizing a two-tiered system of care," he said.

The provision is characterized as affecting only institutional services, but "in our view this proposal would necessarily effectively limit the patient's choice of physician as well," he said. This result is inevitable since patients will be limited to physicians having admitting privileges at the 'Medicaid Hospital.' "

The AMA believes that the Medicaid proposal "is an ill-conceived proposal that would bar Medicaid patients from mainstream medical care," the AMA said. "Any benefits from cost-savings that would be achieved are overcome by the negative impact that this provision would have on the poor through the establishment of a separate health care system for the poor."

******

A proposed provision in the Mental Health Systems Bill that would have provided a "Bill of Rights" for the mental patients has been overwhelmingly defeated on the floor of the Senate.

Senator Robert Morgan (D-NC) with the strong backing of the AMA and the American Psychiatric Association (APA) argued that the private right of action permitted in the provision "will simply serve to encourage frivolous law suits and put the federal courts in the business of reviewing medical decisions on a case-by-case basis."

The measure would have overridden 35 existing state laws and "provide a legal tool to coerce states to spend more money on mental health services," the Senator said in a "Dear Colleague" letter to fellow Senators.

The AMA earlier had dispatched a Legislative Alert urging support of the Morgan Amendment, declaring the Senate Bill "objectionable" as it then stood. The APA feared that court suits by patients would have led to medical treatment decisions by the judiciary, creating serious legal impediments to proper treatments.

The proposed "Bill of Rights" for mental patients, supported by Sen. Edward Kennedy (D-MA), would have given patients the right to refuse treatment and require that their freedom not be unnecessarily restricted, among other provisions.

The overall bill extends and restructures federal aid to community based mental health programs.

******

Legislation now before Congress would block unlimited public access to Professional Standards Review Organization (PSRO) documents.

The AMA has urged Congress as part of its 18-part package of PSRO changes to specify that PSROs are not federal agencies and therefore not subject to requirements of the Freedom of Information Law.

A Court of Appeals decision is pending on the issue in Washington, D.C.

The PSRO provision is part of the Medicare-Medicaid amendments measure approved by the House Commerce and Ways and Means Committees. Though it does not take the non-federal agency route of the AMA proposal, the amendment's procedures for court orders to obtain information would serve much the same effect.

Seven of 25 AMA-developed PSRO amendments were substantially adopted in the last Congress.

The 18 amendments pending would authorize organizations, including foundations, designated by Medical Societies to be specifically eligible for consideration as PSROs; and authorizing of physician polling on agreements between PSROs and the government. Many current provisions relating to PSRO operations would be deleted or modifed under the AMA proposals.

******

Chiropractic students would be eligible for the first time for Federal Health Manpower loans under legislation approved by the Senate Human Resources Committee.

The provision, by Committee Chairman Harrison Williams (D-NJ), was part of the Health Professions

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Prepared by the Washington, D.C.
Office of the American Medical Association

Education Assistance bill sent to the Senate Floor. The AMA and allied health groups protested that the Committee should have deferred the issue pending hearing and testimony. The provision does not make schools of Chiropractic eligible for federal support. The Committee called on the government to study the safety and efficacy of Chiropractic.

The overall Manpower Bill approved by the Committee sharply restricts federal capitation aid for medical schools. However, it is less sweeping than a three year phase-down adopted by the House Commerce Committee.

Complications arising out of budget deadlines may result in Congress approving a one year continuing resolution of aid for medical schools at their current level for the fiscal year starting in October, with other provisions of the congressional legislation taking effect after that date.

A House-Senate Conference may be required to settle the differences between the House and Senate bills on Chiropractic, capitation and many other issues.

******

The AMA has challenged proposed regulations to revise utilization review procedures for Medicare and Medicaid.

In a statement to the Health Care Financing Administration (HCFA), the AMA said "the overall effect of the proposed regulations does not meet the basic criteria for an appropriate program in providing necessary flexibility and fulfilling the intent of Congress."

HCFA was told that certain provisions lack operational flexibility, and that specific standards relating to pre-admission and concurrent review, as well as those relating to prior approval of elective surgery and other procedures," go beyond the authority established in the Social Security Act.

The definition of "major diagnostic or therapeutic procedure" is "unacceptably broad," according to the AMA.

The sweeping authority to allow UR committees to disapprove elective surgery or other major elective diagnostic or therapeutic procedures is inconsistent with the Social Security Act which provides that the government shall not interfere with the practice of medicine, said the AMA.

******

President Carter has signed into law legislation providing higer pay for military physicians. The measure allows bonuses of $9,000 - $10,000 to physicians in the military as well as variable special pay depending on years of service, payment for board certification and incentive special pay for critical specialities. The extra pay could total up to $33,000 on top of regular pay. A discretionary special pay provision for Public Health Service physicians was included in the measure. President Carter had vetoed an earlier military pay bill because of provisions for non-military physicians and non-physicians. The measure was backed by the American Medical Association.

******

The active ingredient in marijuana, called THC, may be okayed by the Food and Drug Administration this fall for restricted distribution use by cancer patients in order to reduce nausea caused by chemotherapy.

An FDA advisory panel voted five to four to make the synthetic product available at cancer treatment centers and medical school hospitals.

The AMA told the FDA that research on use of THC as an antiemetic should be pursued in broader clinical trials. "It appears that the effectiveness data accumulated to date warrants more widespread use of THC for this single purpose in selected patients," wrote James Sammons, M.D., AMA Executive Vice President.

The AMA commended the coordinated efforts at the federal level "to bring to practitioners and patients some hope of relief from the mentally and physically debilitating side effects of cancer chemotherapy."

Although the advisory committee action was a boost for patient groups seeking marijuana, some argued that the synthetic product involved is much less efficacious than the natural product.

******

The Supreme Court decision on Medicaid abortion funding may have an impact on federal policies toward all beneficiaries.

In effect, the high Court said Congress has the right to impose restrictions on benefits that might be available to the general public.

By a 5-4 vote, the Justices upheld Congress' restrictions on Medicaid abortions, limiting federal payment to abortions needed to save the lives of mothers or in cases of rape or incest.

The so-called Hyde Amendment, after Rep. Henry Hyde (R-IL), has plunged Congress into annual debate for four years, with the Amendment forces winning out each time. As a result of the Hyde Amendment, Medicaid-funded abortions have dropped from 300,000 before 1976 to less than 2000 last year.

Pro-abortion and anti-abortion forces have collided bitterly on the issue and opportuned Congress unceasingly. More congressional mail has been generated on abortion than on any other subject.

The Court's ruling came as the Health and Human Services Department was studying what constitutes "reasonable and necessary" medical services that Medicare and Medicaid should finance. Another federal study involves heart transplantation and how and whether Medicare patients should be reimbursed for the procedure.

AMA's Principles of Medical Ethics (New)

The following are the new principles of medical ethics adopted by the AMA House of Delegates at the Annual Meeting on July 24, 1980:

Preamble

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.

II. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.

V. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.

VII. A physician shall recognize a responsibility to participate in activities contributing to an improved community.

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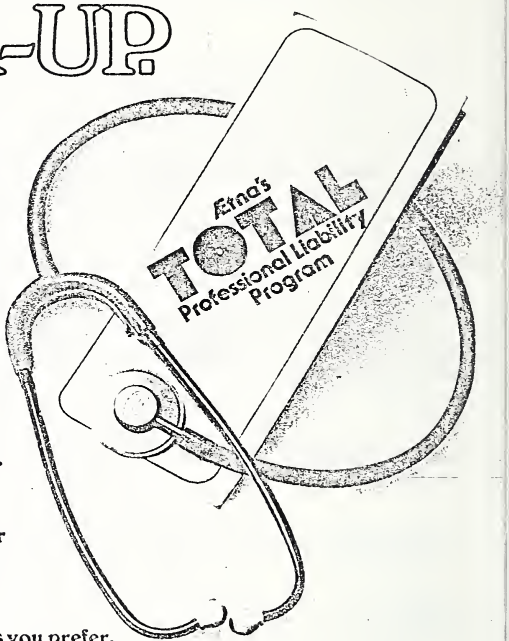

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The President's Page

The Connecticut delegation to the annual and interim meetings of the House of Delegates of the American Medical Association consists of three delegates, three alternate delegates, the president, the president-elect, and Connecticut members of A.M.A. councils. Participation in these delegations is a real privilege and pleasure. The meetings are exciting and informative. The House of Delegates meetings begin Sunday with the usual reports, speakers and introduction of business. Monday is devoted to reference committees. The House resumes its meetings Tuesday, Wednesday, and Thursday. Many delegates arrive early Friday night and Saturday morning for Student and Resident sections, the Auxiliary, the Association of State Medical Society Officers, Council, Trustee and other meetings, and the interviewing of candidates for office. The New England delegation has morning caucuses beginning Sunday morning and each following morning as early as 6:30 or 7:00 o'clock, and at lunch on Sunday and Monday, as well as informal meetings in the New England suite. Afternoon hours from 5:00 to 8:00 each day are spent in numerous receptions pushing the candidacies of favorite sons. Beneficial or not, the receptions do provide an excellent opportunity to meet and talk with physicians from all over the country.

In spite of the long hours and extensive business, attendance is excellent. 99.6% (all but one) of the delegates were still present and seated Thursday morning when the last session began. Even at 6:30 A.M. almost every delegate is there on time. Participation in caucuses, reference committees, and on the floor of the House is excellent. Widely divergent views are debated without rancor or personality. Due largely to the excellent leadership of House Speakers William Rial and Harrison Rogers, the House proceeds expeditiously and democratically. Two hundred forty-eight items of business, including 91 reports and 157 resolutions were considered and acted on in Chicago in July.

Reports consist primarily of responses to various resolutions presented in the past and vary from the report on the budget to an 186-page study with a 9-page report on H.M.O.'s. Forty-four of the reports were prepared by the trustees, the remaining come from the various councils. With few exceptions (I thought the report on physician remuneration singularly poor), these reports include excellent studies and reviews. The studies contain most of the scientific facts available and the reviews generally summarize exhaustive searches through the literature. Connecticut's major resolution on bio-ethics and the A.M.A. Mission for the Eighties did not fare as well as we had hoped, but it is not dead. It was the first item of business on the first day, coming just before the debate on the revised ethics.

One cannot attend one of these meetings without being immensely impressed with the dedication of the delegates, with the operation of the A.M.A. staff, by the quality and quantity of work done by the trustees and councils, and most of all by the efficiency and democratic operation of the entire organization. It is unfortunate that all physicians do not have an opportunity to attend one of these meetings as active participants. I can think of no better way to bring the realization to all physicians that the A.M.A. is a most democratic national organization, and that we physicians have created a remarkable staff organization in Chicago and in Washington which is indeed devoted to the interests of American medicine as directed by the House of Delegates. One is impressed that there is room for wide variations in political, religious, social and economic viewpoints within the A.M.A. The opportunity for change in the national organization, as well as in the state and local organizations, exists for all those devoted to participation in a democratic society.

The large number of constructive and positive activities of the A.M.A are well illustrated during these meetings. One is aware of the very positive role the A.M.A. has played in creating and maintaining the quality of medical practice in the United States. All physicians and health professionals, as well as patients, benefit extensively from the activities of the American Medical Association. It is hard to understand why many physicians do not provide their share of support through membership.

W. Raymond James, M.D.
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Reflections from the Dean's Office

Medical Ethicists or Ethical Physicians?

ROBERT U. MASSEY, M.D.

Curriculum committees sitting down to work this month will be looking for ways to squeeze out more time for medical ethics from those 2,000 hours in the medical student's first two years.

The medical humanities are an ascending constellation, and while those who teach them disagree about what it comprises, they know they must vie with the unified six sciences for precious curriculum hours.

In his Shattuck Lecture, 1980, Daniel Callahan ascribes interest in medical ethics to public concern with professional behavior, to increasing attention by newspapers and television, to the cost of health care, to uneasiness about technology, and to a perception that the system is inhumane, and that it deals with problems which in the past were not considered to be medical.

Within the profession interest has grown because of moral issues raised by new technologies, concerns about the care of the newborn and the dying, questions about using psychotropic drugs, anxieties about the right uses of genetic knowledge, and worries over the equity and distribution of medical care.

Callahan suggests that there may be deeper reasons than those he has listed:

"When questions of ethics are widely and heatedly discussed, it is a good rule of thumb to assume that some larger cultural process is taking place, of which a concern with morality is only one symptom."[1]

It interests me that we see this anxiety about values at the very time when others see a society in moral decline. Perhaps this is the kind of complementarity we should expect. But there is no clean-cut complementarity; no puritan movement standing against a dissolute society; no Augustine against Imperial Rome, but rather moralists accommodating to a secular society.

The unresolvable debates between the relativists and the absolutists will go on; do values change with the times or the situation, or are they eternal? Ought teachers of ethics to espouse values, or should they teach only about values? Will any morality do as long as it can be explained in the categories of behavioral science? Of course it all depends upon standpoints; but standpoints may be points above an infinity apart.

Troublesome stuff for curriculum committees. It may be safer to study history; the medical historians say so. They say that medical history makes for good stories, and that students will draw their own conclusions about the dangers of dogmatism in science, or the power of an idea to set the course for a life or an age.

Perhaps the novelists and the playwrights make the deep issues more easily understood than anyone. T.S. Eliot's "The Cocktail Party" suggests moral dilemmas and compels expressions of fundamental beliefs with an efficiency unmatched by any case study or ethical analysis. Just ask who Sir Henry Harcourt-Reilly is.

Medical students are as caught up in the ethical issues of the late twentieth century as are their faculty and their practicing colleagues. They want serious talk about values, though they lack the time, and most of them the inclination, to master the scholarly language and jargon of formal ethics.

When humanism was literary culture, and science was natural philosophy, the two were distinct in the curriculum and in the minds of their exponents. They are rediscovering each other. Dr. George Sarton wrote, as early as 1927, that "science must become more humanistic and humanism must include science."[2]

In that inclusive sense ethics embraces all of medicine, for essentially medicine is the expression of an ethical relationship between physician and patient. That is not all that medicine is, nor is that all that there is to the ethics of medicine, but the physician must understand the implications of that relationship if he is to be a *good* physician.

Clearly definitions are called for, but there is not enough time for them. The relativist-absolutist debate cannot be resolved, either here or in the classroom. Shaw, Lewis, and others who know about these things have said that it is still being argued in Hell.

For medical ethics, or ethics in general, to work, however, there should be some agreement about what is meant by the idea of virtue. In any discussion about how ethical decisions are made, someone needs to mention that *character* is the element that carries the day when all else fails.

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Abortion 1980: The Debate Continues

JOSEPH M. HEALEY, J.D.

Seven years after the United States Supreme Court's decisions in *Roe v. Wade*[1] and *Doe v. Bolton,*[2] abortion still remains the center of a bitter societal struggle over what American public policy should be. During its most recent term, the United States Supreme Court reviewed two cases focussing on the extent to which individual states and the federal government had an obligation to fund medically necessary abortions. The first case, *Harris v. McRae,*[3] involved questions concerning the extent to which an individual state is legally required to fund abortions not covered by federal reimbursement and the extent to which limitations imposed by Congress on the use of federal funds for abortion violated the constitutional rights of the woman seeking abortion. The second case, *Williams v. Zbaraz,*[4] raised questions concerning the extent to which a state may impose its own limitations on the use of funds to support abortion. Many of the issues in the second case were similar to, and treated in the same manner as, those raised by the first case. Together, they reflect the continuing absence of consensus in our society about this most difficult problem.

Mr. Justice Stewart delivered the opinions in both cases for a divided Court (5-4). The cornerstone of his decisions is an understanding of the Medicaid program and of the nature of the rights created in the earlier abortion cases. The Medicaid program is described by Stewart as a federal-state partnership in which federal financial assistance is provided through the states to eligible individuals who obtain health care services covered by the program. His review of the history of Medicaid uncovered no evidence of a Congressional intent to impose upon individual states a legal obligation to provide services which the federal government would not reimburse. Individual states were free, if they wished, to provide such services at their own expense. Congress was free, if it wished, to amend the Medicaid statutes to impose such an obligation on the states in the future. However, Stewart found no current basis for requiring states to provide such services. States, therefore, have no legal obligation to provide funding for abortions, even medically necessary abortions, which were ineligible for federal reimbursement.

The Constitutional rights of women to have abortions funded either by the individual states or by the federal government were considered by Stewart to be severely limited by the nature of the rights established in the previous abortion cases. In essence, the majority of the Court considered the right of the woman to be a right to choose to terminate abortion without excessive government interference. This right does not include a Constitutional entitlement to the financial resources necessary to allow her to exercise her choice. The government may not place obstacles in the woman's path, but it has no obligation to remove obstacles it did not create, such as indigency. The right established in the abortion cases is a shield against unjustified state interference not a sword to compel the state to provide services.

Viewed in this light, limitations upon the use of federal funds to support abortions except in limited circumstances represent legitimate legislative policies which do not violate the Constitutional rights of the woman seeking an abortion. Neither the concept of "due process," nor the concept of "equal protection" nor either of the First Amendment's guarantees of religious freedom was recognized by the Court as a source of an obligation for the Federal Government or the state to pay for all medically necessary abortions. The Court went one step further and added that funding restrictions imposed by individual states comparable to those in the federal sector likewise did not violate any Constitutional rights of women seeking abortions.

In these two cases, as in other recent abortion decisions, the Court is emphasizing the political nature of the context in which the right to abortion may be exercised. The United States Congress and the legislatures of the individual states have power to shape this context, especially aspects relating to funding. This recognition, however, is also a reminder that since widespread difference of opinion remains and both abortion advocates and abortion opponents are attempting to use political force to shape the political context, the abortion debate is unlikely to abate in the foreseeable future.

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1. 410 U.S. 113 (1973)
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3. 48 LW 4941 (1980)
4. 48 LW 4957 (1980)

JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

Getting Together–Just For The Health Of It

Please pardon our repetition, but we are again asking your cooperation.

This will be the third year that five major statewide health organizations are pooling their resources during the month of September in a combined effort to provide information people can use to improve their "lifestyle."

Once again we have launched a multi-media public awareness campaign designed to draw attention to the major factors which a person can control to increase chances of living a healthier, longer life.

We feel we have developed a successful formula of placing emphasis on proper eating habits, encouragement to stop smoking, exercise, learning to cope with stress, and blood pressure awareness.

Also for the third consecutive year, Governor Grasso has designated September LIFESTYLE AWARENESS MONTH, and the Lifestyle Council of Connecticut is continuing to make available six easy-to-read folders which are sent free to anyone requesting them.

In addition, health experts from each of the five organizations will appear on radio and TV news and public affairs programs during the month discussing the subjects both as single entities and in combination with each other.

Many of you have helped us the past two years and we hope you will repeat this fine cooperation.

The key to the success of the Council's goal is mass distribution and you are in a vital position to help by placing copies of these folders in your waiting room.

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EDITORIALS

Contemporary Ethics for the '80s

Together with the explosion of technological advances in medicine there has been a corresponding resurgence of interest in medical ethics.

Medical ethics, in its traditional meaning, deals with the value-related problems that arise in a patient-physician relationship. The patient-centered ethic has long been stressed in all our ethical statements dating back to the code of Hammurabi in 2500 B.C. Even today it remains so sensitive, so emotionally charged, and so critical to life that meticulous attention to detail, clear distinction, and critical surveillance is required. More recently, broader issues are being raised by those outside the profession, questioning even that commitment: the increase in public concern regarding the sheer size and scope of our health care programs with its escalating costs and the drain on available public funds; disagreements regarding allocation of health resources; the expressed discontent with access, quality and cost of medical care; the general uneasiness with all of our new technology; and finally, social pressures from the public demanding that the health care system now solve many totally unrelated community problems.

The old goals are being questioned and new moral dilemmas are being created by an emerging technology faster than we can generate answers. These new questions demonstrate a need to make policy decisions for large groups, even whole populations, and thus will raise new and extraordinarily complex moral decisions for the profession. It is difficult enough to practice any complex discipline such as medicine when there is an agreement between goals and purposes. When moral problems are combined with uncertainty concerning professional purposes, the stage is set for considerable anxiety, suspicion, and resistance on the part of the profession. A modern ethical code is vital to the profession and to all biomedical sciences in order to protect the integrity of our humanistic heritage and provide a moral legacy for those to follow.

In answer to the need for a program of relevant and contemporary ethics, the AMA, after more than two years of extensive debate and study, has approved a new set of "Principles of Medical Ethics" which is published in its entirety elsewhere in this issue. The preamble, with its seven statements, is a positive statement of contemporary ideals representing a true break with the past. Gender has been deleted and specific prohibitions have been replaced with demands for positive action by physicians. The revision consists of clear statements establishing broad areas of responsibility for all physicians and emphasizing the belief that ethical standards are developed for the benefit of the patient. Each principle relates to each other and stresses positive action on the part of each physician while delineating the magnitude of each one's commitment. Careful scrutiny will show that no major issue of importance to the patient or profession has been ignored or omitted. The principles address the problems of discipline, integrity, due process, implementation of function while preserving rights of physicians, and stressing the independent responsibility as a citizen. This new statement is not merely a sop to our critics or legal advisors. It is positive evidence that we are responding to the present social reality by recognizing and adapting to changing concepts, changing institutions, and a changing array of health care professionals.

No statement of principles can stand without interpretation. The principles are the foundation upon which future opinions and reports of the Judicial Council will be based. We will be judged on how these ethical statements are applied to specific instances.

Ours is a great heritage. Medicine has been aptly described as the most humane of the sciences and the most scientific of the humanities. Acceptance and support of the new principles by all physicians is in keeping with that heritage.

Guy W. Van Syckle, M.D.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Professional Negligence—Connecticut 1980

Many members are still reeling from the shock of the size of the increase in their malpractice premiums for the coming year. The premiums, about a 70% increase, varying from about $2,500 to $20,000, are the bottom line—dollars to be treated as a business expense, to be passed on to the public. However, suits are more than money; they represent personal tragedies for many patients and physicians, and their families.

Even after reading the report in this issue many may still be skeptical as to the legitimacy of the size of the increases. Some still believe that Aetna is making exorbitant profits, even a rip-off. However, an out-of-state expert consultant hired by CSMS, who studied the report and listened with the CSMS Malpractice Committee to the Aetna presentation, called it "fair." The report at least should convince a reader that there has been a sudden and serious deterioration in the problem, that cases are increasing both in number and severity, and also, that the outlook seems to be for the worse. Even the Aetna actuarians miscalculated the magnitude of the problem.

It is not so much the cases of $25,000 or less, but the increasing incidence of cases $250,000, $500,000 and even over $1 million that are responsible—all within the last year or two. Among the nine states covered by Aetna, Connecticut used to be among the lowest in number and severity of cases; it is now among the highest. What are the reasons, particularly because, with justification, Connecticut physicians consider the quality of medical care in the state among the highest? Inflation certainly has its effect. And significantly, some lawyers in the state have become expert by specialization in the field. Our American society is becoming more litigious in all fields. No longer are patients reluctant to sue their doctors, who must now consider a patient as a potential plaintiff and the medical record as a potential legal document. Technology and complicated invasive surgical procedures carry greater risks and complications; premiums reflect the specialties most involved. Publication of jury verdicts and awards influence the public and future juries.

The crisis has occurred in spite of our traditional peer review system, emphasis on CME, and increasing consciousness of the ever-present danger of suits. And in addition to these are Aetna's seminars, brochures, videotapes, and claims analysis studies. The area Claim Defense Panels, which began in 1971, have had some educational value to the 850 physicians who have participated in over 375 cases.

Is there a solution? CSMS and Aetna jointly are suggesting to hospital medical staffs a Patient Injury Prevention Plan (PIP) whose aim is to "reduce the incidence of patient injury attributed to cognitive, clinical, or management deficits" in patient care. Some will say that this is being done already. But the PIP program will be based on actual malpractice cases selected by Aetna for their educational value. They will be "sterilized" to eliminate any identifying markers. Also, to qualify for a reduction in premiums, hospitals must accept the Quality Assurance program recently formulated by the Joint Commission on Accreditation of Hospitals.

Independently of PIP, the time has come for every medical staff to consider setting up a special malpractice committee to scrutinize every suit brought against a member of the staff, from the time it is initiated. This crisis, and this is the proper word, should overcome reluctance by medical staffs to such a procedure, analogous to the area Claim Defense Panels. At least 80% of malpractice cases in the state originate in hospitals.

To my knowledge, there are only two hospitals that have such a committee. It is not to be confused with the Loss Prevention and Education program, a hospital administrative committee, concerned with hospital incidents, though physicians increasingly are joined with hospitals in malpractice suits. Setting up such a committee should be staff action, assisted in its formulation by one or more of the 850 or so physicians who have participated in panel reviews. The purpose of Claim Defense Panels is to assess the quality of medical care in a suit, arrived at by secret ballot, for the benefit of an attending, but not participating, lawyer who is defending the physician. Whereas panel action is set in motion at the request of Aetna or the defendant physician who appears to answer questions, the trigger for the suggested hospital malpractice committee would be the recording of a malpractice suit by a plaintiff-lawyer by a writ of complaint in the court of jurisdiction.

Whereas the proceedings of a hospital committee, like the Claim Defense Panels, should be confidential until resolution of the suit, the information derived from a hospital committee proceeding should be used for compelling reasons, such as correction of a physician's behavior and protection of patient care.

In the final analysis, any success in ameliorating the program will require the effort of *every* physician in the program. Any award against an individual physician is paid for by the entire membership.

Fred Fabro, M.D.

In Memoriam

BROWN, MARION R.S., Temple University, 1943. Dr. Brown was a general practitioner in the New Haven area since 1944 and served as the Meriden school health officer for 10 years. She was also a staff physician at the Masonic Home and Hospital in Wallingford since 1974 and was a member of the Meriden Medical Society, the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Brown died June 17, 1980 at the age of 61.

BYRNE, DAVID W., Columbia University, College of Physicians & Surgeons, 1927. Dr. Byrne was a urologist in the Hartford area since 1929 and was co-director of the urology department at Hartford Hospital for many years before his retirement in 1965. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Byrne died June 25, 1980 at the age of 77.

CASHMAN, JUSTIN L., Hahnemann Medical School, 1937. Dr. Cashman was a general practitioner in the New Haven area since 1938. He was a 1933 graduate of Fordham University and was elected to the Hall of Fame of Fordham University. He also served as a flight surgeon in the U.S. Navy during World War II. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Cashman died June 12, 1980 at the age of 67.

CHOBIAN, JOSEPH A., Loyola Medical School, 1933. Dr. Chobian was a general practitioner in the New Haven area since 1934 until his retirement 10 years ago. During World War II he served as a captain in the medical corps in Europe. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; he was also an honorary member of the staff of Griffin Hospital. Dr. Chobian died July 28, 1980, at the age of 72.

CLARK, ISAIAH, Albany Medical College, 1965. Dr. Clark was a internist in the Hartford area since 1967. He served in the U.S. Army Medical Corps during the Vietnam War, returning to Hartford to work for about five years in the inner-city Community Health Services Clinic before going into private practice. He was on the staff of Hartford and Mt. Sinai Hospitals, and was a part-time physician at Weaver High School. Dr. Clark was a member of the Hartford County Medical Association and the Connecticut State Medical Society. He died July 3, 1980 at the age of 44.

DIAMOND, EDWARD H., University of Breslau, Germany, 1932. Dr. Diamond was a enterologist in the Fairfield area since 1934. He served in the U.S. Army Medical Department during World War II as a captain and was an honorary attending surgeon on the staff of Norwalk Hospital. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Diamond died June 4, 1980, at the age of 74.

DIGNAM, BERNARD S., Yale Medical School, 1935. Dr. Dignam was a cardiologist in the Hartford area since 1936, and was plant physician at the former Bigelow-Sanford Company. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Dignam died June 19, 1980, at the age of 72.

MURPHY, JOHN C., Columbia College of Physicians and Surgeons, 1932. Dr. Murphy was chief of surgery at Danbury Hospital between 1952 and 1958. In 1966, he moved back to New York City where he practiced medicine at Veterans Administration Hospital until 1972. He was a major in the Army Air Force in World War II and was among the first 300 members elected to the American Board of Surgery. Dr. Murphy died July 2, 1980 at the age of 74.

RUSSELL, THOMAS H., Yale Medical School, 1910. Dr. Russell was a surgeon in the New Haven area since 1912 until his retirement. From 1915 to 1917 he served as a lieutenant in the U.S. Navy Medical Corps. In 1915 he became an attending surgeon at Grace Hospital. During succeeding years, he was first consulting surgeon and then, in 1938, became chief of staff. He served in that capacity until 1945 when Grace Hospital merged with New Haven Hospital. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Russell died June 30, 1980, at the age of 94.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Opportunity to rent professional office, 100 Retreat Avenue, Hartford, CT. 575 sq. ft., close proximity Hartford Hospital. Available mid-September. Inquiries to William B. Laakso, M.D., 549-1900.

To lease modern medical office space. 800 sq. ft. Can be shared with another doctor. Contact: Thomas J. Mirabile, M.D., 100 Retreat Avenue, Hartford, CT.

Aetna Life & Casualty needs an Associate Medical Director in its Employee Health Services Department. Candidate will conduct employee physicals and perform administrative duties. Applicants must be MD's that have or are eligible for a license to practice medicine in CT. Send resume and salary requirements to Bill McKendree, Recruiting Office, Aetna Life and Casualty, 79 Farmington Ave., Hartford, CT 06156. EOE.

EMERGENCY ROOM

Full service community hospital in suburban setting has openings for physicians with ER experience. Positions are part time varied shifts and replacement for vacations. Competitive salary package. Please respond to Dr. E. Bundy, Director, Emergency Room, Meriden-Wallingford Hospital, 181 Cook Avenue, Meriden, CT 06450.

FAMILY PRACTICE

Wanted: Part time physician. General Practice, Internist, Family Practice. 8:00 to 12:00 five mornings a week with night and weekend coverage on rotation. Conn. licensed. Masonic Home and Hospital, Wallingford, CT.

INTERNAL MEDICINE

Gastroenterologist to join an established Gastroenterologist in a Hartford suburb, pop. 50,000 with a 300 bed hospital. Send CV to CSMS/IM-Gast. ALK.

PHYSICANS WISHING TO LOCATE IN CONNECTICUT

ALLERGY

Available within one month of acceptance: Age 36. Applied for Conn. license. FLEX. AB-cert. Presently in practice. MD: India. Int.: Lakewood Hosp., Ohio. Res.: St. Vincent's Hosp., NY. Fellowship: West Jersey Hosp., NJ. Four years experience in England. Bd. cert. in Allergy and Immunology and ped. Also trained in adult allergy. Solo practice desired in large or med. size community in CT. Contact CSMS/Allergy-AJS.

ANESTHESIA

General Practice and part time Anesthesia: Available now. Age 41. Presently in practice. AB-elig. MD, int. and surg. res.: King George Med. Coll., Lucknow Univ., Lucknow. Anes. res.: French and Polyclinic Med. Ctr., NY and Monmouth Med. Ctr., NJ. Will consider all types of practice in CT. Virendra Singh, M.D., 564 Goodwater Street, P.O. Box 26, Jenkins, KY 41537.

DERMATOLOGY

Available now. Age 37. Conn. license. Nat'l. bds., elig. MD: St. Univ. of Buffalo. Int.: Mt. Sinai Hosp., NY. Res.: NY Hosp.-Cornell. Looking for part or full time position in private or grp. practice, clinic, hosp., or other setting. Contact CSMS/Derm.-CLS.

July '81. Age 30. Conn. license. Nat'l. bds., cert.-IM; elig.-Derm. MD: SUNY. Int. and res.: (IM) Hartford Hosp. Fellowship: (Derm.) Mt. Sinai Med. Ctr., Miami. Solo, grp. or assoc. type practice in large community in CT. Elliot C. Zweig, M.D., 14310 NE 5 Place, North Miami, FLA 33161.

FAMILY MEDICINE

Jan. '81. Age 28. Nat'l. bds., elig. 1/81. DO: Chicago Coll. of Osteopathic Med. Int. and res.: Chicago Osteopathic Hosp. (IM & FM) grp. or assoc. practice in med. community. Jeffrey A. Mills, D.O., 3326 W. 184th St., Apt. 2-South, Homewood, IL 60430.

July '81. Age 37. AB-elig. '81. MD: Autonomous Univ. of Guadalajara. Int. and res.: St. Joseph's Hosp., Stamford, CT. Grp. practice in large or med. community. Paul Berman, M.D., 1425 Bedord St., Apt. 7P, Stamford, CT 06905.

Available now. Age 28. Nat'l. bds., elig. MD: SUNY Brooklyn-Downstate. Int. and res.: Southside-Bayshore Hosp., NY. Solo practice in med. community. Prefers town of 15,000-25,000, Southeast or Northwest CT. Will have physicians' assistant who will be working with him. Michael Karp., M.D., 40-172 West 4th St., Patchogue, NY 11772.

July '81. Age 26. Nat'l. bds., elig. MD: Boston Univ. Int. and res.: Univ. of Maryland. Fellowship: Faculty Development-Univ. of MD Hosp. HMO or clinic setting with opportunity for academic affil. Husband is Internist. Paula Ann Leonard-Schwartz, M.D., 3410 Carriage Hill Circle, #202, Randallstown, MD 21133.

July '81. Age 27. Nat'l. bds., elig. '81. MD: Brown Univ. Int. and res.: Overlook Hosp.-Columbia Univ. Solo, grp. or assoc. practice desired. Stephen M. Upham, M.D., 193 Morris Ave., Summit, NJ 07901.

Aug. '81. Age 28. Nat'l. bds., cert. Presently in practice. MD: Georgetown Univ. Int. and res.: Chestnut Hill Hosp., PA. Solo, grp. or institutional practice desired in med. community. Would be particularly interested in a faculty position in a FM residency, either as in-house attending faculty or as preceptor through my office. Lawrence L. Ward, M.D., P.O. Box 59, Fort DeFiance, AZ 86504.

Family Practice and Psychosomatic Medicine: Available immediately. Age 52, AB-elig. MD: Univ. of Minnesota. Int.: Santa Maria, CA. Res.: Santa Barbara, CA. FAA examiner since 1959. Senior examiner for seven insurance companies. Consultant Psychosomatic Med. Adm. Dir./Med. Dir., Churchill Mem. Hosp.; Exec. V.P. and Dir., Solar Lab., Los Angeles. Dir. in charge planning, General Medical Corp. Will consider all types of practice in CT. Bruce R. Little, M.D., 881 Indian Hill Rd., Orange, CT 06477.

INDUSTRIAL MEDICINE

School Health: Dec. '80. Age 37. Conn. license. FLEX. Presently in practice. DO: Coll. of Osteopathic Med. and Surg., Iowa. Int.: Naval Regional Med. Ct., CA. Grp. institutional, industrial or school health in med. community. Contact CSMS/Ind.Med.-MJM.

INTERNAL MEDICINE

Summer/Fall '80. Age 32. AB-cert. MD: Tulane. Int. and res.: Childrens and Adult Med. Ctr., San Francisco, CA. Grp. or assoc. practice in large or med. community. Prefer general IM of both inpatient and outpatient in either assoc. or single specialty group. Michael M. McShane, M.D., Route #1, Box 275, Mt. Vernon, MO 65712.

The Evolution of a Hospital

Sherwin B. Nuland, M.D., Guest Editor

Raphe—the word is derived from ancient Hebrew, and refers to a seam, a junction, a line at which tissues join and are fused into strength. Therefore it was, to the Israelites, the root of the word *heal.* Rapha-El, God's Healer—an angel to the Jews, a saint to the Catholics, and a divine mission to all physicians, whether believers or skeptics. Be it the biblical God, the God of the questing lay philosophers or the God that is the search for truth in all of us, we need to identify with Raphael and carry that ministry to the bedsides of those who have entrusted themselves to our care. For though it has become fashionable to denigrate physicians, to accuse us, to disperse our aura and to categorize us with the technicians, we know that there is something divine in our calling. The most grizzled objectivist among us is aware that we are the bearers of a sacred trust, that within each of us is a repository of reverence for life and a sense of our privileged obligation to heal. In our best moments, the extent of that moral privilege is a source of awed humility for us; at our worst we abuse our franchise.

When Dr. William Verdi began planning his Catholic hospital in the early years of this century, he conceived of an institution where well-trained physicians, without reference to their ethnic or social credentials, could join in a ministry to the sick. We don't know whose idea it was to name it the Hospital of St. Raphael, or even whether that inspired person had any idea of the suitability of the name's derivation. What we do know is that in the 72 years since the hospital doors opened in 1908 the trust has been kept and the mission brought to ever broader levels of accomplishment.

Verdi was no cockeyed idealist, and we should have no illusions about his other great motive: this most intrepid and skillful of surgeons needed a workshop in which to explore unhindered the extent to which his wide-ranging talents could develop the daring operations that were just beginning to emerge in the great European and American clinics. After leaving Yale, Verdi had studied pathology with Rudolf Virchow, he had seen first-hand how the modern techniques were being applied in the German-speaking clinics, and he was on close terms with such leaders of American surgery as Rudolf Matas and the Mayo brothers. At a time when the chairman at Yale, Joseph Marshall Flint, had chosen to make his own contributions in the laboratory and in the area of teaching, the great clinical surgery in Connecticut was being done by William Verdi at the Hospital of St. Raphael. He was equally at home in all parts of the body; he was a thoracic surgeon, a neurosurgeon, an abdominal, urological, gynecologic and head-and-neck surgeon; it has been said that by the mid-1940's the only operation no one had ever seen him do was a tonsillectomy. He did everything with great skill and a certain panache that was the envy of less dextrous operators.

Although it was Dr. Verdi's intention to bring the best of contemporary medicine to the people of Connecticut, he could never have anticipated that his hospital would one day become a superb training ground for young physicians. For, though Guglielmo Francesco Verdi was born in a small village on the Bay of Naples, he was the archetypal Germanic *Geheimrat.* He led, he innovated, one could learn from his example, but he did not formally teach. The Hospital of St. Raphael was primarily a *doing* hospital, and remained so until the 1950's. But over the past 25 years it has emerged as one of the strongest clinical training centers in the state, in almost all specialties. This came about because a group of far-seeing and highly trained physicians began to direct the various departments and sections at about the time that illness removed Verdi from the scene. This innovation took place originally in Radiology, Internal Medicine, Pathology, and General, Thoracic and Neurologic Surgery, and later spread to other departments and subspecialties. Devoted nurturing by that handful of original leaders has resulted in clinical sections of exceptional strength and depth. Three of those leaders have contributed publications to this issue.

Another outcome that Dr. Verdi could not have anticipated was the quality of the clinical research that would be done in his institution. Most of the articles in this issue are examples of the kind of important contributions that can be made by busy practitioners seemingly flooded by the streams and torrents of the daily round. With the exception of Dr. Lee's paper, all of the studies described in this special issue have been done by workers who are basically astute clinicians. In each case the objective eye of the clinical researcher and the keenly trained mind of the practicing physician have combined to make valuable observations and to critique the results of their own carefully controlled patient management. In the scrupulous appraisal of their techniques and outcomes the various authors have set high standards for themselves, but no higher than those of their day-to-day hospital work.

Dr. Lee's study is a research contribution of considerable import. His work had received national recognition even before he came to the Hospital of St. Raphael, and it is gratifying that he should be able to continue to pursue such significant determinations in a community setting., The atmosphere of scientific curiosity that has been fostered within the department of Pathology is of great support to Dr. Lee's efforts, but it is an atmosphere that pervades the more clinical services as well. There is a certain quality of the Academy at this institution, in the sense of its atmosphere of medical scholarship.

Finally, attention must be drawn to Dr. Shapiro's editorial. Ironic it is, that having been among the first of the St. Raphael's departments to achieve a position of excellence, the Radiology service should be deprived by bureaucratic fiat of one of its most important diagnostic tools. Although his tone is muted by sensible discretion and an admirable degree of tact, Dr. Shapiro is leading the hospital's exhausting campaign against an arrogance of power that has cut a wide swath through the medical community of this state. This is no angel he is wrestling against— it is the frightening power of ignorance in action.

And so, the vision of William Verdi has evolved into an institution that is more than he bargained for; it is many things to many people: a great center of healing for the people of Connecticut, a fine teaching hospital for its residents and students, and an academy of clinical science for its staff. Now that St. Raphael's is embroiled in a snarling conflict with the political watchdogs over cost containment, it has everything; it is the *compleat* modern hospital.

So far from being detrimental, the teaching of physicians and students is distinctly advantageous to a hospital and its patients. The teaching hospital is in general more influential, more widely useful and more productive in contributions to medical knowledge than a hospital not concerned with teaching. Such a hospital is more attractive to physicians and surgeons of distinction and, therefore, more likely to be able to attach such men to its attending staff, and thereby secure the best medical service.

—William Henry Welch, M.D., in an address delivered at the opening of Jefferson Medical College, Philadelphia, 1907.

The work of an institution in which there is no teaching is rarely first class. There is not that keen interest, nor the thorough study of the cases, nor amid the exigencies of the busy life is the hospital physician able to escape clinical slovenliness unless he teaches and in turn is taught by assistants and students. It is, I think, safe to say that in a hospital with students in the wards the patients are more carefully looked after, their diseases are more fully studied and fewer mistakes made.

—Sir William Osler, "The Hospital as a College," address delivered to the New York Academy of Medicine, 1903.

Intraoperative Cholangiography: A Reappraisal

VENKATACHALA I. SREENIVAS, M.D. AND
ORLANDO PELLICCIA, JR., M.D.

ABSTRACT—Intraoperative cholangiography was performed in eighty consecutive patients who underwent cholecystectomy for biliary calculus disease. Of the twenty-six patients with indications for common duct exploration, the cholangiogram was negative in thirteen (fifty percent) and helped in avoiding unnecessary duct exploration. In one instance, calculi in the ducts was detected among the fifty-four patients having no indications for common duct exploration. There was one false positive and one false negative examination. The low incidence of false positive and false negative examinations is indicative of the reliability of the technique. Intraoperative cholangiography is helpful in avoiding unnecessary duct exploration in patients with clinical indications for the exploration, but not cost-effective in detecting stones in patients without indications for duct exploration.

Although intraoperative cholangiography (IOC) has been in vogue for nearly fifty years, its value in the management of patients with biliary calculus disease is still disputed. Proponents for the routine use of IOC claim that the procedure has several advantages: (a) detecting bile duct stones whose presence is not suspected from lack of clinical or laboratory evidence indicative of their presence; (b) avoiding duct exploration in some of the patients suspected of having stones in the duct based on clinical and laboratory criteria; (c) demonstrating concomitant abnormalities and anatomic variations; (d) the procedure is safe and easy to perform.[1, 2, 3, 4] Opponents of routine IOC, on the contrary, point out that (a) the procedure is not always easy to perform; (b) there is danger of injuring the bile ducts during attempts at performing the procedure; (c) the operation is prolonged; (d) radiologic visualization of the ducts does not eliminate the need for careful dissection; (e) false positive examinations lead to unnecessary duct exploration with its associated increase in mortality and morbidity; (f) the procedure is not cost-effective.[5, 6, 7]

The following prospective study was undertaken to assess the advantages and disadvantages of routine IOC in the management of patients undergoing cholecystectomy for biliary calculus disease.

Patient Population

Consecutive patients undergoing cholecystectomy since June, 1977 are included in the study. In every instance, IOC was performed by one of the authors. There were 26 males and 54 females and their age distribution is shown in Table 1. Of the 80 patients in the study, 26 had indications for duct exploration based on the criteria shown in Table 2.

Table 1

AGE DISTRIBUTION

Age in Years	*No. of Patients*
1-10	0
11-20	1
21-30	10
31-40	3
41-50	10
51-60	18
61-70	21
71-80	15
81-90	2
91>	0

VENKATACHALA I. SREENIVAS, M.D., Director of Surgical Education. ORLANDO PELLICIA, JR., M.D., Chairman; both of the Department of Surgery, The Hospital of St. Raphael.

Table 2

INDICATIONS FOR BILE DUCT EXPLORATION

1. Abnormal liver function tests. (Elevated bilirubin, enzymes, and alkaline phosphatase).
2. History of cholangitis or pancreatitis.
3. Dilated common bile duct (> 1 cm).
4. Palpable stones within the ducts.

Technique

Prior to the commencement of the operation, an x-ray of the right upper quadrant is obtained with the patient slightly rotated to the right side. This film is evaluated as to positioning and adequacy of exposure. After dissecting the gallbladder from its bed and tracing the cystic duct to its junction with the common hepatic duct, the cystic duct is cannulated with a No. 17 or 19 cholangiocatheter (Deseret Pharmaceutical Company, Inc.) and secured in place with a ligature tied around the cystic duct. Cholangiograms are obtained with the patient in 5-10° Trendelenberg position after injecting 1, 3, and 10 ml of 50% Hypaque® (sodium diatrizoate). Following evaluation of these films, additional films are obtained with further injection of the contrast material and or by changing the position of the patient if necessary for adequate examination of the biliary ducts. For a cholangiogram to be considered normal, the ducts should be free from filling defects, the intrahepatic biliary radicles adequately visualized, the common duct at its largest diameter should not exceed 1 cm., and the contrast material should flow freely into the duodenum. Cholangiograms, after being viewed by the surgeon, are sent for interpretation by a radiologist who reports his findings to the surgeon.

Particular attention is paid to avoid introducing air bubbles into the duct and to prevent movement during exposure of the films. Prior to its insertion into the cystic duct, the cholangiocatheter is connected to a three-way stopcock and filled with saline. During insertion, the catheter is slowly but steadily flushed with saline by an assistant. After insertion of the catheter, the syringe containing the contrast material is connected to the third limb of the three-way stopcock. Usually an air bubble is trapped between the third limb of the stopcock and the syringe containing the contrast material. This air bubble is displaced by flushing 1-2 ml of the dye into the syringe containing saline through the stopcock. To minimize turbulence in the duct, the contrast material is injected slowly and allowed to settle for 1-2 minutes before the films are exposed. During exposure of the films, the patient is maintained in a state of apnea by the anesthesiologist.

Results

IOC was successfully performed in each of the 80 patients in the study. There were no technical failures nor complications referable to the procedure. The average time required for the completion of the study (including the radiologist's report) was 20 minutes. Of the 26 patients in whom duct exploration was indicated on the basis of clinical and laboratory criteria, in 13 (50%), the cholangiogram was normal. In this group of 13 patients with normal cholangiograms, duct exploration was not performed and to this date none of these patients have developed clinical features referable to common duct stones. In the entire group of 80 patients, there was one false-positive and one false-negative examination. The patient with the false-positive study had clinical and laboratory criteria for duct exploration. The dye failed to flow into the duodenum and at exploration of the duct no stones were found. In the patient with false-negative study, stones were identified in the pre-exploratory cholangiogram. Postexploratory cholangiogram at the conclusion of duct exploration was considered normal both by the surgeon and the radiologist. However, T-tube cholangiogram on the tenth postoperative day showed stones in the common bile duct (Figure 1). On retrospective examination of the films, it was noted that the left hepatic duct was not visualized at the time of operation, probably due to impaction with stones, which subsequently escaped into the common duct (Figure 2). Of the 54 patients without clinical or laboratory indications for common duct exploration, one was found to have stones measuring approximately 3 mm in the common duct (Figure 3). The fate of these stones, had they not been recognized and removed, is a matter of speculation. It is conceivable that they might have spontaneously passed through the ampulla of vater.

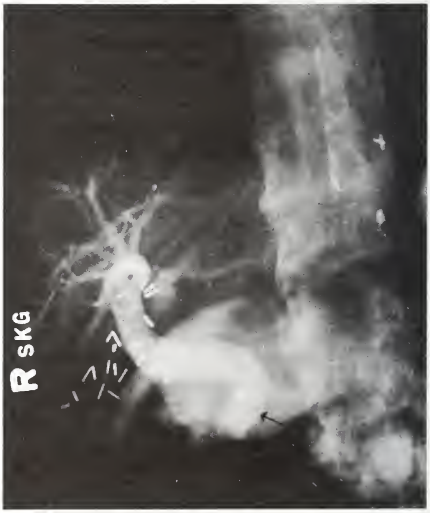

Figure 1
Stones demonstrated on T-tube cholangiogram

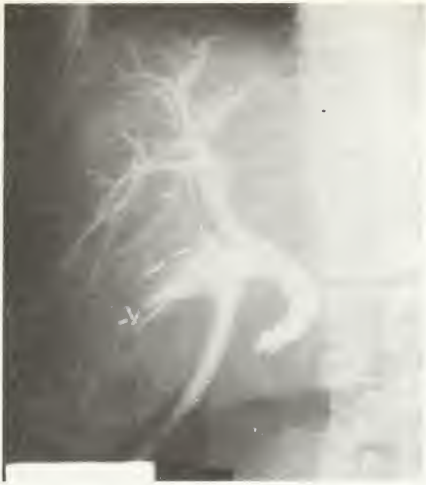

Figure 2
Nonvisualized left duct in which stones were left behind

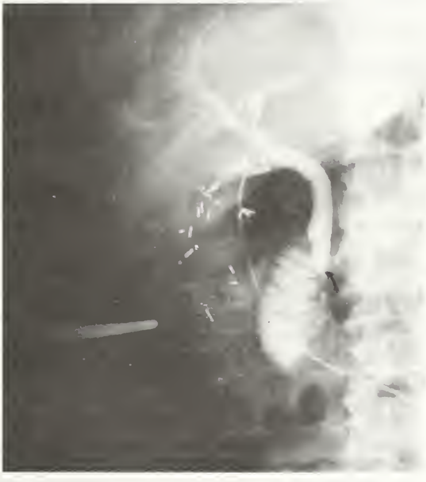

Figure 3
Small stones in a patient in whom criteria for duct exploration were absent.

Discussion

The absence of complications attributable to IOC in this study attests to its safety. The examination was successfully performed in every patient in whom it was attempted and is not a difficult procedure to perform. The incidence of false-positive and false-negative results in reported series varies and is, at least in part, dependent on the meticulousness with which the procedure was performed.[5,8,9] The low incidence of false-positive and false-negative examinations in the present study (2.5% for the entire series) reflects the reliability of the technique employed.

The procedure is most helpful in avoiding unnecessary duct exploration in the group of patients with clinical and laboratory criteria for duct exploration (Table 2). In this group of patients, addition of cholangiography decreased the number of duct explorations by half. It may be argued that the examination in patients with normal cholangiograms but with clinical and laboratory indications for duct exploration is indeed false-negative and, hence, stones are missed. Such an occurrence cannot be completely refuted by the present study, but is most unlikely. Studies by Chapman has shown a close correlation between normal cholangiogram and absence of stones in the ducts.[10] From his study he concluded that ducts are apt to be free from stones when cholangiographic findings are normal. It is known that when ducts are explored for stones on the basis of clinical and laboratory considerations, stones are found in only approximately 50% of the patients.[11] It is of interest that in the present study, by employing cholangiography, duct exploration was avoided in 50% of patients who had clinical and laboratory criteria for exploring the duct. Therefore, it is not unreasonable to assume that had the ducts been explored when cholangiograms were normal, no stones would have been found and the examination is truly normal.

One of the reasons advocated for performing routine IOC is to detect stones at the time of cholecystectomy in patients without clinical or laboratory evidence of biliary duct stones. The reported incidence of such stones varies from 1.2-14%.[4] In the present study the unsuspected stone was detected in one out of 54 patients (1.8%). IOC, on an average, increased the cost of cholecystectomy by $200 per patient. The total cost of cholangiography in the 54 patients without clinical or laboratory indications for duct exploration amounted to (200 x 54)=$10,800. In other words, to detect unsuspected stones in a patient, the expenditure incurred is $10,800. If we assume that cholangiography had not been performed in this group of 54 patients and the patient in whom the stone would have been left behind needed subsequent exploration for its removal, the estimated cost of re-exploration, including hospital and professional fees, would be $3,700. Considered from financial aspect only, re-exploration for an unsuspected stone costs $7,100 less compared to its detection by the use of routine cholangiography and, therefore, is not cost-effective.

Conclusions

1. IOC is not a difficult technique and is safe.
2. It has a high degree of accuracy, when done with technique described.

3. It is most beneficial in patients suspected of having common duct stones and decreases common duct exploration by approximately 50%.
4. It is not cost-effective for detecting stones whose presence is not suspected by clinical or laboratory findings.

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Coronary Artery Bypass at The Hospital of St. Raphael: Early and Late Results of the Cardiothoracic Group of New Haven

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GEORGE L. WILSON, M.D. AND MAX G. CARTER, M.D.

Coronary artery bypass has become an accepted method of treatment for angina pectoris. Although it is clearly effective in providing symptomatic,[1,2] and objective[3,4] relief of ischemia in the majority of patients, its role in improving survival is still debated on the basis of the randomized VA study performed during their early experience with coronary revascularization.[5] Our experience at the Hospital of St. Raphael shows that considerably better results can be obtained at the present time.

Indications for Operation

The primary indication for myocardial revascularization was disabling angina pectoris, although some patients were operated upon for cardiac failure related to ventricular aneurysm, ventricular septal perforation papillary muscle rupture or dysfunction, or combined valvular and ischemic heart disease. Patients with mild symptoms were encouraged to pursue medical management, particularly if single or double vessel disease was present. In contrast, higher risk patients with poor ventricular function were revascularized when the coexistence of significant angina suggested the possibility of reversible ischemic cardiomyopathy. Patients with unstable angina as defined by persistent chest pain at rest in the hospital despite maximal therapy with beta blockers and nitrates were treated with intra-aortic balloon pumping followed by urgent catheterization and surgery.

Surgical Technique

The patients were all monitored with percutaneous radial artery and Swan-Ganz catheters during the operation. The greater saphenous vein was generally harvested from the lower leg in order that there would be less discrepancy between the size of the graft and the

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coronary arteries. When satisfactory leg veins were unavailable due to prior vein stripping, we used veins from the arm, rather than the internal mammary artery because of the limited flow supplied by the pedicled mammary graft. The proximal anastomoses to the ascending aorta were constructed prior to instituting cardiopulmonary bypass with a tangentially applied vascular clamp on the aorta in order to minimize the duration of extracorporeal circulation. When indicated for transient ischemic attacks, carotid endarterectomy preceded cardiopulmonary bypass. A Harvey bubble oxygenator was used with moderate hypothermia at 30°C for cardiopulmonary bypass. Hemodilution with flow of 2.4 L/min. was utilized. Cannulation incorporated ascending aortic and right atrial catheters with left ventricular venting via the right superior pulmonary vein. The distal anastomoses were accomplished during a single period of aortic cross clamping with cold (4°C) cardioplegic protection of the myocardium by infusion into the aortic root (Figure 1). Additionally, the heart was bathed in iced saline solution to achieve rapid cooling of the myocardium. One to six distal anastomoses were done (Table 1), with the intention of revascularizing each branch of adequate caliber ($>$ 1 - 1.5 mm.) involved with stenoses of $>$ 70% reduction in cross-sectional area. The technique of using sequential grafts (one vein anastomosed side-to-side to two or more arteries) has enhanced our ability to revascularize all significant lesions (Figure 2).

Table 1
NUMBER OF GRAFTS PERFORMED

	Coronary Bypass Alone	*Combined Procedures*
Single	8	9
Double	41	8
Triple	48	2
Quadruple	18	
Quintuple	3	
Sextuple	1	
Total:	119	19

Mean: 2.75 grafts/patient

Patients and Operations

One hundred thirty-eight patients underwent coronary bypass by the Cardiothoracic Group of New Haven in the one year period between July 1st, 1978 and June 30th, 1979. Although in the subsequent year (1979-1980) we have done 212 coronary bypass procedures, we wished to select a series with 1-2 years follow-up in order to assess the late results of surgery. It must be emphasized that no patients have been excluded from the series because of high risk factors or complex procedures such as coronary bypass combined with left ventricular aneurysmectomy, single or multiple valve replacements, or carotid endarterectomy. Of the 138 patients, 80.4% were men, and 19.6% were women. The mean age was 58.7 years. In the

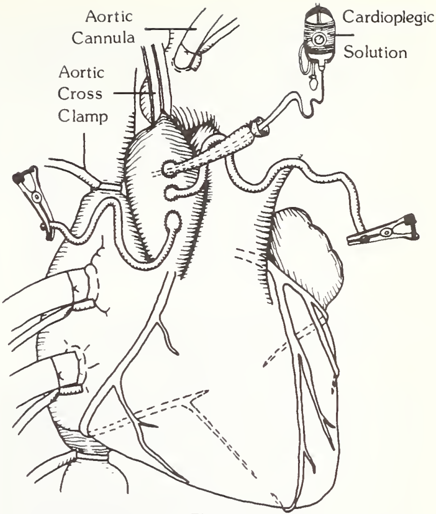

Figure 1
The heart-lung machine perfuses the body via the aortic cannula. The aortic cross clamp interrupts the perfusion of the coronary arteries during the construction of the distal coronary anastomoses. During this time the heart is cooled and protected by the infusion of cardioplegic solution into the aortic root through a catheter threaded temporarily into one of the vein grafts.

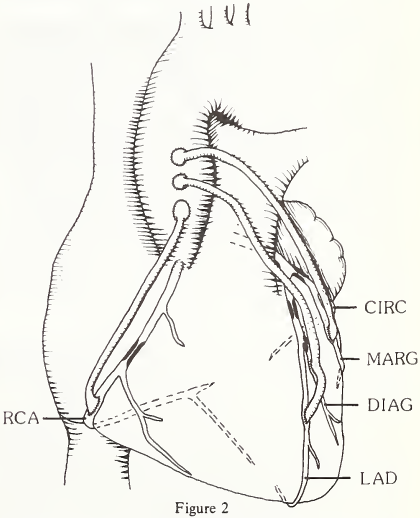

Figure 2
Sequential bypass has been done with side to side anastomosis to the diagonal branch (DIAG) and end to side anastomosis to the left anterior descending (LAD). Also illustrated are individual bypasses to the right coronary (RCA) and to the marginal branch (MARG) of the circumflex coronary artery (CIRC).

group with coronary bypass only, 2.75 grafts were placed per patient (Table 1). The risk of coronary surgery is largely related to preoperative left ventricular dysfunction.[6] Table 2 shows the state of the left ventricle as judged by ejection fraction and left ventricular end diastolic pressure, in our series.

Table 2
LEFT VENTRICULAR FUNCTION

EF %	*% of Patients*	*Impairment*	*LVEDP mm. Hg.*	*% of Patients*
> 55	46%	Normal	< 12	31%
35-55	38%	Moderate	13-18	43%
< 35	16%	Severe	> 18	26%

Legend:
EF - ejection fraction
LVEDP - left ventricular end diastolic pressure

Early Results

Operative Mortality: Operative mortality was defined by death occurring intraoperatively or within 30 days of the operation. Of the 138 patients, two such deaths occurred, one in a patient with reoperation for coronary artery disease who required the intra-aortic balloon pump preoperatively for unstable angina, and the other in a patient with acute transmural infarction, acute mitral insufficiency, pulmonary edema, and cardiogenic shock, who also had preoperative balloon support before undergoing mitral valve replacement and double coronary bypass. Therefore, the total operative mortality was 1.4%, both deaths occurring in high risk patients.

Perioperative Myocardial Infarction: Myocardial infarction was ordinarily defined by new Q waves on the postoperative electrocardiogram. However, total CPK and CPK-MB were also obtained on the first two postoperative days and in cases of discrepancy, the patient's cardiologist decided about infarction. Perioperative infarction occurred in 5 patients or 3.6%.

Reexploration for Bleeding: No patients were reexplored for bleeding during this study period.

Perioperative Stroke: Two mild cerebrovascular accidents occurred in the perioperative period (1.4%). Neither of these patients had concomitant carotid endarterectomy. Both patients have made virtually complete recovery of neurologic function.

Wound Complications: Four patients experienced either mild cellulitis or wound infection of a leg incision (one balloon site, 3 vein donor sites—2.9%). There were no chest wound infections or dehiscences.

Post Cardiotomy Syndrome: Seven patients had presumed post cardiotomy syndrome. This syndrome was characterized by fever, pericarditis type of chest pain, and moderate leukocytosis which responded in each case to therapy with Indomethicin.

Late Results

Late Mortality (Cardiac or Otherwise): There have been 5 late deaths in the entire group. Three patients died during the first postoperative year and two have died during the second postoperative year. Using actuarial statistics for the numbers of patients at risk during these intervals, the cumulative one year survival including operative mortality was 96.6% while that for two years was 94.6%. In comparison to the VA Cooperative Study, our survival curve for patients having coronary revascularization alone for stable angina was 100% at one month, 99% at one year, and 98% at two years (Figure 3), essentially identical to the normal survival curve for patients of this age.

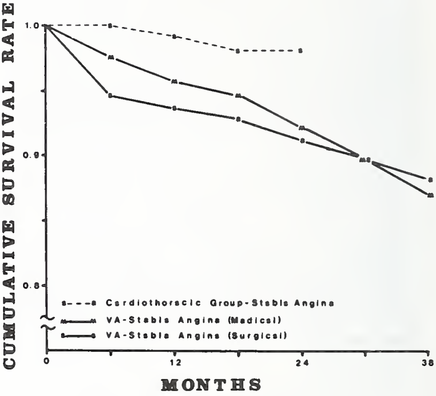

Figure 3
Cumulative survival rates with stable angina pectoris.

Symptomatic Status and Late Infarction: Follow-up was complete for all 138 patients in the series. All survivors were contacted by phone in June, 1980, in addition to the periodic office visits obtained by the surgeon. Each patient was questioned about any symptoms of chest pain, and was rated as asymptomatic, improved but with mild angina, no change, or worse, compared to preoperative status. Of the 131 survivors, 110 were asymptomatic (79%), 23 consider themselves to be improved (17%), while 5 are unchanged (3.8%). The mean follow-up was 1.4 years.

Our patients were carefully questioned by phone survey about any hospitalizations for possible cardiac problems and these admissions checked for any evidence of late myocardial infarction. Since many infarctions may be clinically silent, each patient also had periodic electrocardiograms in the office, which were carefully screened by a cardiologist for new Q waves. Only three patients developed late infarctions, two by electrocardiogram and one presumed by clinical history at the time of death.

Discussion

We have experienced a gradual reduction in operative mortality as we have broadened our indications for coronary bypass to include patients with angina who have poor ventricular function (some with ejection fractions less than 0.25), or with combined coronary and carotid disease. We attribute these results to our increasing experience, use of cold cardioplegia with topical hypothermia, and microvascular technique. In coronary artery bypass uncomplicated by valvular disease or reoperation, our 0% mortality compares favorably to the current experience in Houston (2.2%)[7] or Cleveland (1%)[8] with the same category of patients. Perioperative infarction as evidenced by the appearance of new Q waves has previously been reported to occur in 5-15% of cases.[2] Perioperative infarction is considered benign by some clinicians but this is a controversial subject. With the newer techniques of myocardial protection, we are seeing a fall in this complication correlating with the fall in operative mortality. Similarly, our incidence of other postoperative complications, such as postoperative bleeding, sternal dehiscence, stroke, or wound infection, is quite low by national standards.[8]

Since the primary indication for coronary artery surgery is disabling angina pectoris, the symptomatic response to surgery is very important. Averaging most studies, 70% of patients enjoy complete relief of symptoms, while another 15% experience significant improvement.[2, 9] Our finding 96% of the survivors to be improved or asymptomatic at 1.4 years mean follow-up attests to the value of the operation for patients with coronary disease who are unduly restricted in life style.

Athough the duration of follow-up is quite short in this series of patients, the actuarial survival and incidence of late postoperative myocardial infarction compares very favorably to those of previously reported studies[1, 9, 10] and particularly the VA Cooperative series.[5] It is to be hoped that as the operative techniques become even more refined, we will continue to see improvement in long term survival and freedom from late myocardial infarction.

Summary

Coronary heart disease is one of the major problems in the United States today. Surgical treatment of coronary disease can be safely and efficiently accomplished in selected community hospitals. Coronary bypass has proven valuable in the relief of angina pectoris and hopefully, as more investigations are made, its role in survival for coronary patients without left main disease will become clarified.

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Estrogen and Progesterone Receptors in Breast Cancer: A New Approach to Measure

SIN HANG LEE, M.D., F.R.C.P.(C)*

ABSTRACT—Estrogen and progesterone receptor activity of breast cancer cells is demonstrated in cryostat frozen sections, using hydrophilic fluorescent steroid hormone conjugates as histochemical receptor tracers. With this technique, the percentage of the receptor-positive cells in a cancer cell population can be estimated, and serves as a numerical function indicative of a physiologic status of the malignant epithelial components in the tumor. Since the cancer cells instead of extractable proteins are used as a common denominator for comparison, concomitant noncancerous tissue components do not interfere with the quantitative interpretation. The histochemical findings on cancer cell receptor activity can be closely correlated with the cytosol receptor protein values obtained with a dextran-coated-charcoal method in 80% of the tumors. This new technique provides a potentially more accurate, inexpensive and efficient way of selecting patients with receptor-positive cancer for endocrine therapy.

Introduction

The standard systemic treatment for patients with advanced breast cancer is either hormonal manipulation or chemotherapy, or combinations of these approaches. Hormonal manipulation is a preferred modality of treatment because it generally produces less toxic side effects than chemotherapy. However, only 20-30% of patients with spreading breast cancer will benefit from this form of treatment.[1, 2] Therefore, there is a need for development of methods to predict *a priori* whether a cancer is in fact a hormone-responsive tumor before therapy is instituted.

For the past ten years, assay of estrogen receptor proteins in the supernatant of tumor tissue homogenates, so-called cytosol, has been found to be valuable as a means to identify potential hormone-responsive cases. An objective remission rate of 32-60%[3, 4] among those patients with estrogen receptor-positive breast cancer has been obtained, compared to a 20-30% response rate among patients selected by clinical criteria alone. But it is only a partial success because about half of the patients with estrogen receptor-positive breast cancer fail to respond to hormonal therapy, and approximately 10% of the cancers with a negative estrogen receptor value still respond favorably to some form of endocrine manipulation. These results indicate that further improvement of the methodolgy of estrogen receptor assays is necessary.

The inherent shortcoming of the cytosol receptor assay is that it measures the steroid-binding capacity of all proteins extracted in the tumor tissue homogenate. Since surgical specimens of human breast cancer are never homogeneous in cellular composition, the results of these tests are influenced by the content of the epithelial component in the specimen, the percentage of the cancer cell receptor proteins extractable and the proteins extractable from other noncancerous tissue components. Consequently, variations in these factors alone may contribute to wide fluctuations of the final deduced estrogen receptor values, not always reflecting true physiologic states of the cancer cell population.

Histochemical techniques on the other hand enable hormone-binding activity to be observed directly over

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the individual cancer cells in a frozen section; thus cancer cells with a significant amount of steroid receptors can be distinguished from the receptor-negative ones microscopically. Since the number of cancer cells observed is used as the common denominator for a semiquantitative comparison, concomitant noncancerous components do not interfere with the results.

This communication summarizes the findings on estrogen and progesterone receptor status of breast cancers as encountered in a community hospital, using fluorescent hydrophilic macromolecules of steroid derivatives as receptor tracers.

Materials and Methods

The histochemical reagents used to localize the receptors were fluorescent estradiol conjugate (Figure 1) and fluorescent progesterone conjugate (Figure 2). These were hydrophilic macromolecules each consisting of a bovine serum albumin molecule labeled with 25-30 steroid residues and 4-8 fluorescein or rhodamine dye derivatives. The estradiol conjugate emitted a green, and the progesterone conjugate emitted an orange-red fluorescence because they carried different dyes. Therefore both estrogen and progesterone receptors were detected simultaneously after a cryostat frozen section had been stained with a mixture of these two reagents. The details of the histochemical techniques have been published elsewhere.[5, 6]

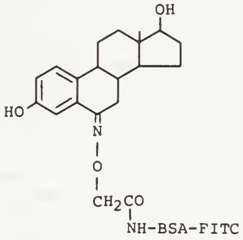

Figure 1
Fluorescent estradiol conjugate (17β-estradiol-6-carboxymethyl oxime-bovine serum albumin-fluorescein isothiocyanate)

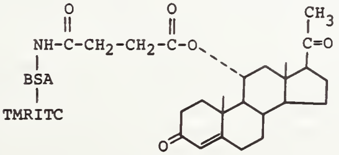

Figure 2
Fluorescent progesterone conjugate (11α-hydroxy-progesterone hemisuccinate-bovine serum albumin-tetramethylrhodamine isothiocyanate)

A total of 126 specimens of breast cancer were studied along with other benign lesions which were used as controls. These specimens were surgically removed from patients at the Hospital of St. Raphael for therapeutic or diagnostic purpose, and submitted to the pathology laboratory for routine tissue examination. None of these patients had received prior hormonal, radiation or other forms of chemical cancer therapy. The histochemical findings on each breast cancer were expressed as percentages of estrogen receptor-positive and progesterone receptor-positive cells in the cancer cell population.

In order to correlate the histochemical observations with the cytosol assays, a portion of each tumor specimen was sent to an independent laboratory for estrogen and progesterone receptor protein determination.

Results

The histochemical assays showed that the cytoplasm of benign epithelial cells of the mammary ducts and lobules, including those involved in fibrocystic mastopathy, fibroadenoma and intraductal papilloma, manifested varying degrees of estrogen- and progesterone-binding capacity. Most estrogen receptor-positive epithelial cells appeared to be also progesterone receptor-positive though the intensity of the two spectra of fluorescence did not always fluctuate to the same extent from cell to cell.[7]

About 85% of the breast cancers examined were composed of fluorescent and non-fluorescent cancer cells mixed in different proportions after staining with the fluorescent estradiol conjugate. The cancer cells in the remaining 15% of tumors were totally non-fluorescent.[7] This indicates that human breast cancers are either completely estrogen receptor-negative, or composed of heterogeneous cancer cell populations in terms of estrogen binding capacity. There appear to be no breast cancers in which all the cancer cells are estrogen receptor-positive. An example of such cancer cell heterogeneity is illustrated in Figures 3 and 4.

When the tumors were categorized according to the percentages of receptor-positive cancer cells observed, it was realized that only in 19.7% (6) to 23% (7) of the tumors did the number of estrogen receptor-positive cancer cells either equal or exceed that of the estrogen receptor-positive ones. Compared to the number of the estrogen receptor-positive ones, that of the progesterone receptor-positive cancer cells in a tumor was usually slightly lower.[6] Based on these histochemical findings, if one may assume that containing a significant amount of estrogen or progesterone receptors is prerequisite for the cancer cells to be susceptible to hormonal manipulation, it would be easy to accept the statistic reality that only one in four or five human breast cancers shows clinically a 50% (or more) gross reduction of the tumor mass with endocrine therapy.

One obvious question to ask is how closely the

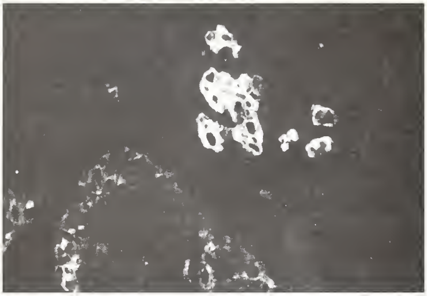

Figure 3
Cryostat frozen section of a breast cancer stained with fluorescent estradiol conjugate. Several small groups of cancer cells near the center of the photomicrograph are estrogen receptor-positive. The cancer cells in the left lower part are receptor-negative. X 250

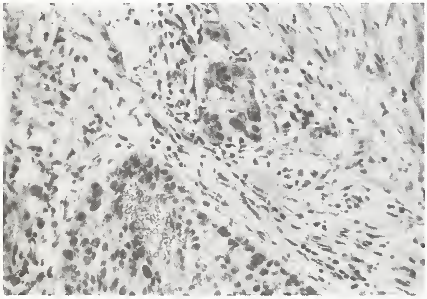

Figure 4
A consecutive cryostat frozen section adjacent to that shown in Fig. 3 to demonstrate the cancer cells in the same area. H&E. X 250

histochemical findings on the receptor status of a tumor can be correlated with the cytosol assay of receptor proteins. Two previous reports[6, 7] indicated that there was a lack of parallel correlation between these two sets of data when the cytosol assays were conducted in a local laboratory using a polyacrylamide gel filtration method. Most recently, the tumor cytosol assays have been performed in another reference laboratory** which uses the standard dextran-coated-charcoal method. A preliminary result showed that there was a good correlation in this new series between the percentages of receptor-positive tumor cells and the cytosol receptor protein values in 11 of the 14 tumor specimens tested (Table 1) when a 50% receptor-positive cell population was used as a cut-off figure to divide receptor-negative and receptor-positive cancers. Discrepancies were noted in cases 1021, 1083 and 1700. In case 1021, the histochemical findings showed a 60% estrogen receptor-positive and a 40% progesterone receptor-positive cancer cell population, yet the cytosol assay demonstrated progesterone receptor proteins only. In case 1083 and case 1700, there was a very low percentage of progesterone receptor-positive cancer cells; but a medium range of progesterone receptor protein value was reported. It is interesting to point out that in all these three cases the cytosol assays failed to demonstrate estrogen receptor proteins, an unusual finding in the presence of tumor progesterone receptors.[4, 8]

Table 1

COMPARISON OF TUMOR CELL AND CYTOSOL RECEPTOR VALUES

		% Tumor Cells				*Cytosol (femtomoles/mg protein)*	
Case No.	*Age*	*Estrogen Receptor*		*Progesterone Receptor*		*Estrogen Receptor*	*Progesterone Receptor*
		+	−	+	−		
655	55	2	98	2	98	X	X
926	67	30	70	30	70	X	X
1021	78	60	40	40	60	X	114
1034	73	5	95	5	95	X	X
1083	69	3	97	3	97	X	58
1234	54	5	95	1	99	X	X
1235	55	1	99	0	100	X	X
1240	81	1	99	1	99	X	
1420	70	50	50	30	70	43	53
1513	44	0	100	0	100	X	X
1640	85	85	15	85	15	48	110
1697	76	1	99	1	99	X	X
1700	48	7	93	7	93	X	83
1880	75	90	10	50	50	115	59

+ Positive

− Negative

X = Femtomoles + kd were indeterminate

Another point of interest is that case 1640 was an intraductal papilloma with no evidence of malignancy. However, both the histochemical and the cytosol assays demonstrated a significant level of estrogen and progesterone receptors in the specimen. This is one of many examples to show that receptor proteins extractable from benign epithelial cells, if the latter are present in significant quantities in a cancer specimen, may actually cause false positive results in a truly receptor-negative cancer when cytosol assays alone are used.

Discussion

When estrogen receptor was first recognized as a potential marker for identification of hormone-responsive breast cancers, tumors were arbitrarily labeled as either receptor-positive or receptor-negative. However, the accuracy of using this qualitative designation to predict clinical response to endocrine therapy is only about 50%,[3, 4] a rather disappointing result. In order to increase the value of this marker as a means for patient selection, attempts have been made to quantitate the estrogen receptor proteins in tissue homogenates[3, 8] and to measure, in addition, progesterone receptor proteins as a second marker[4, 9] with varying degrees of success. Yet the most difficult task of performing quantitative tests on the homogenate of tissues highly heterogeneous in cellular composition is to find a basis for comparison since the extractable proteins, DNA and the wet weight of the tissues are not a true common denominator among different specimens. Recognizing this problem, several investigators[10-12] have tried to develop histochemical techniques to observe steroid binding activity of the cancer cells directly with a microscope, using cancer cells as the common denominator. Although these early attempts have not evolved into useful and practical technology, the soundness of this approach has been subsequently proved by the observation that not only the cancer cells (which may vary greatly in receptor contents from focus to focus in a tumor), but the hyperplastic and papillomatous benign ductal epithelial cells indeed contain a significant amount of receptors.[7] Tests designed to measure ingredients in tissue homogenates simply cannot distinguish the cellular origins of the receptor proteins.

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The author wishes to thank Dr. Patricia Luhan, Department of Pathology, Mount Sinai Hospital, Hartford, Connecticut, for the performance of the cytosol receptor protein assays with the dextran-coated-charcoal method.

Another advantage of using histochemical assays is that they can assess the cellular receptor status of the intraductal and the infiltrating cancer separately. Obviously, if both coexist, the physiologic state of the infiltrating cancer will play a more decisive role in determining the prognosis and the appropriate modality of treatment for the patients than that of the intraductal lesion. A previous report has already pointed out that except in papillary cancers, the intraductal carcinomas are usually estrogen receptor-negative even when coexisting with receptor-positive infiltrating cancer cells in the vicinity.

In making correlations between biochemical and histochemical assay results, the method used for biochemical determination of the receptor proteins appears crucial. When a polyacrylamide gel filtration method is used, the correlation is found to be poor. With the standard dextran-coated-charcoal method, the biochemical results can be closely correlated with the histochemical findings in about 80% (11/14) of the tumors. In the remaining cases, discrepancies can be explained on the basis of a selective extraction of progesterone receptor proteins from the non-cancerous epithelial cells, or may be due to a poor extraction of estrogen receptor proteins during preparation of the cytosol. The latter possibility has been reported by Skinner.[13]

Because it is easy to use, can produce results in just a few hours after the excisional biopsy, does not need special equipment and yields potentially more accurate information than the currently popular biochemical assays, the histochemical technique for assessment of estrogen and progesterone receptors as presented in this report is being actively evaluated in at least 50 medical centers in this country and abroad. Meaningful results will eventually be derived from joint efforts of the surgical pathologists, surgeons, medical oncologists and biochemists in institutions where there are organized programs for the treatment of advanced breast cancer patients.

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Ultrasound-Guided Liver Biopsy: A Technique for the Tissue Diagnosis of Hepatic Malignancy

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ABSTRACT—Ultrasound-directed liver biopsy is a technique for the tissue diagnosis of primary or metastatic liver disease. The diagnosis of malignancy was made in nine out of twelve patients who underwent this procedure. There were no complications.

This technique is particularly suited for small focal liver lesions and suspected malignancy within the left hepatic lobe, and is safe. It offers advantages over laparoscopy, skinny-needle ultrasound-directed cytology, and mini-laparotomy.

Introduction

Grey-scale ultrasonography has revolutionized our ability to non-invasively image the liver. In experienced hands, this technique can be as accurate as 93% in successfully localizing primary or metastatic disease within the liver.[1]

The authors describe in this report our experience in combining grey-scale ultrasonography with percutaneous needle liver biopsy. This technique appears to be a safe and accurate means for obtaining a tissue diagnosis in suspected primary or metastatic liver disease.

Method

Since November 1977, twelve patients have had grey-scale ultrasound-directed percutaneous liver biopsies performed by the authors at either The Hospital of St. Raphael or Yale-New Haven Hospital. Indications for this biopsy technique included a high clinical suspicion of malignancy, focal or multiple ultrasound scan defects interpreted as primary or metastatic hepatic malignancy, or the need for documentation of malignancy after a standard percutaneous double-pass liver biopsy failed to reveal tumor tissue. In all circumstances, the patients had prior ultrasound scans which had been reviewed by us to determine the feasibility of ultrasound-directed needle biopsy. Prior to biopsy, the procedure was explained to the patient and informed consent obtained. All patients had platelet counts greater than 80,000 prothrombin times not greater than 3 seconds longer than control, and partial thromboplastin times not greater than 45 seconds. The procedure was performed in the ultrasound laboratory. The patient was re-scanned prior to biopsy. The transducer was placed on the skin overlying the lesion and 2 cm markers were projected onto the image (Figure 1). These markers showed the depth of the lesion and the projected needle track in relation to the great vessels and other structures to be avoided. The appropriate distance of needle insertion was then measured on the shaft of a Klatskin needle and a guard placed at this level (Figure 2). The guard prevented deeper penetration than desired on liver puncture. The skin area over the suspected lesion was then cleaned

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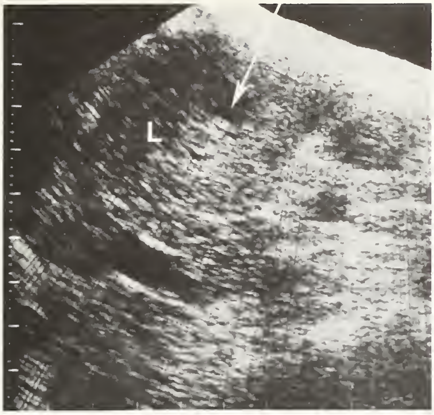


Figure 1
Longitudinal ultrasonogram through the liver (L) showing a definite defect, consistent with metastatic disease in the liver. The direction and position of the needle for biopsy of the left lobe of the liver are shown by the arrow. The 2 cm markers on the left margin of the scan can be used to measure the depth of the lesion.

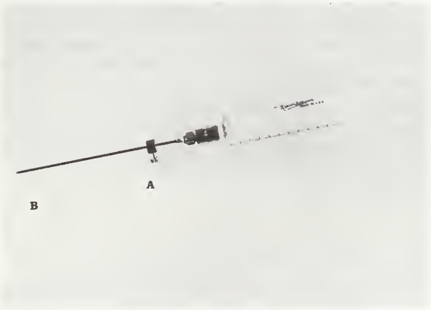


Figure 2
Adjustable guard (A) on shaft of Klatskin needle (B).

with betadine and alcohol and locally infiltrated with 1% Xylocaine. The puncture approach was either through the anterior abdominal wall or a right intercostal space, whichever provided the most direct path to the center of the suspected lesion. The angle of puncture was determined by the angle in which the ultrasound transducer could best localize the defect. It was our preference when using the anterior approach to be perpendicular to the suspected lesion. The liver puncture was performed usually while the patient was in expiration and two passes with a Klatskin needle were made if necessary. The tissue was fixed in formalin promptly.

Results

The results of our initial twelve ultrasound-directed liver biopsies are shown in Table 1. There was a strong clinical suspicion of primary or metastatic malignancy in all twelve patients biopsied.

Table 1

CLINICAL DATA AND RESULTS OF ULTRASOUND DIRECTED LIVER BIOPSY

	Number	*Percent*
Total Patients:	12	
Male	7	
Female	5	
Tissue confirmation of primary or metastatic malignancy by ultrasound directed biopsy:		
Successful	9	75%
Unsuccessful	3	25%
Known history of prior primary malignancy:	6	
No history of prior malignancy:	6	
Types of malignancy confirmed by percutaneous biopsy:		
Adenocarcinoma of the breast	3	
Adenocarcinoma of the pancreas	2	
Hepatocellular carcinoma	2	
Anaplastic bladder carcinoma	1	
Small cell carcinoma from lung	1	
Biopsy approach:		
Anterior subcostal	9	75%
Right intercostal	3	25%
Liver - spleen scan results:		
Defects in right and left lobes	5	
Sole defect right lobe	4	
Sole defect left lobe	2	
Ultrasound results:		
Defects in right and left lobes	6	
Sole defect in left lobe	3	
Sole defect in right lobe	3	
Liver function abnormalities:		
Abnormal	9	75%
Normal	3	25%
Complications:	0	0%

Using this technique a tissue diagnosis of primary or metastatic hepatic malignancy was documented in nine (75%) of our patients. In the 3 patients with negative biopsies, all were found subsequently to have metastatic malignancy, one by laparoscopy and two by mini-laparotomy.

Six of our twelve patients (50%) had recently documented primary malignancies and biopsies were performed in these circumstances for tissue confirmation of metastatic disease. In 4 of the 6 (67%) metastatic disease was confirmed by ultrasound-directed liver biopsy. Of the six patients who had no prior history of malignancy, 5 (83%) were confirmed by ultrasound-directed liver biopsy. Of these patients, 2 had primary hepatocellular carcinoma, 2 had metastatic pancreatic carcinoma, and one had metastatic breast carcinoma.

Nine of our patients had anterior approaches to ultrasound-directed biopsy. Eight of our 9 positive biopsies for malignancy were obtained utilizing a subcostal or subxiphoid approach. There were no complications using this technique since by ultrasound one could direct the biopsy needle away from great vessels, gall bladder, stomach, and other viscera.

99m technetium-sulphur colloid scans in eleven of the twelve patients were interpreted as showing focal or multiple filling defects. However, all twelve patients had abnormal ultrasound examinations of the liver. In 2 patients, additional focal ultrasound defects were also seen in the pancreas. Of the following liver function tests (SGOT, LDH, alkaline phosphatase, bilirubin) at least one was abnormal in 9 of the twelve patients. In both patients with hepatocellular carcinoma, serum alpha fetaprotein levels were elevated.

Discussion

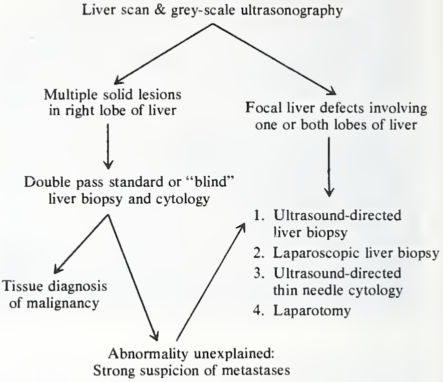
Percutaneous liver biopsy as originally described by Menghini[2,3] traditionally has been a safe and effective means for diagnosing parenchymal liver disease. This technique has been particularly helpful in the rapid evaluation of diffuse metastatic liver disease with an accuracy of approximately 50-70% when combined with hepatic cytology and a "double-pass approach."[4,5] Furthermore, the technique is associated with a low mortality rate (0.02%).[6] However, since the needle is inserted "blindly" into a fixed area of the right lobe, focal areas of hepatic abnormality in the left lobe of the liver or the medial right lobe are easily missed. When this occurs the patient may need to undergo more invasive diagnostic procedures such as laparotomy or laparoscopy in order to obtain a tissue diagnosis.

In experienced hands, grey-scale ultrasonography is able to differentiate between solid and cystic lesions. In addition, it frequently can predict underlying hepatic pathology, i.e., cirrhosis, fat, or tumor. It was thus a natural consequence that this excellent imaging technique would be combined with existing percutaneous liver biopsy techniques to help improve the histologic accuracy in diagnosing metastatic liver disease. In 1972, Rasmussen described the practical aspects of this combination and obtained a 70% positive biopsy result for malignancy on a single pass without cytology.[8]

The results presented in this paper have shown that ultrasound-directed liver biopsy using a Klatskin needle is a simple and accurate means of diagnosing metastatic malignancy to the liver. Our 75% true positive rate improves upon the blind percutaneous accuracy rate because of its ability to biopsy focal lesions in either the right or left hepatic lobe, or small lesions easily missed by blind biopsy. The technique is safe because of the ability to avoid viscer or great vessels as well as its ability to measure depth of puncture.

Table 2

ALGORITHM FOR EVALUATION OF SUSPECTED PRIMARY OR METASTATIC LIVER LESIONS


Liver scan & grey-scale ultrasonography
Multiple solid lesions in right lobe of liver
Focal liver defects involving one or both lobes of liver
Double pass standard or "blind" liver biopsy and cytology
1. Ultrasound-directed liver biopsy
2. Laparoscopic liver biopsy
3. Ultrasound-directed thin needle cytology
4. Laparotomy
Tissue diagnosis of malignancy
Abnormality unexplained: Strong suspicion of metastases

In the work-up of metastatic disease of the liver (Table 2) we feel that if a focal solid ultrasound abnormality is found the first attempt at obtaining a tissue diagnosis should be via an ultrasound-guided percutaneous needle biopsy. This approach should prove to have an advantage over ultrasound-directed fine-needle cytology because a greater amount of tissue is obtained and an expert cytologist is not needed. It also has obvious advantage over laparoscopy and laparotomy in view of its simplicity, relative lack of invasiveness, and inexpensiveness.

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Treadmill Exercise Testing and Thallium-201 Scanning as Indicators of the Presence and Severity of Coronary Artery Disease

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ABSTRACT—A group of 89 patients who underwent both Bruce treadmill exercise testing and Thallium-201 scanning were evaluated by coronary angiography. A positive stress test and positive Thallium-201 scan had a sensitivity of 90%, a specificity of 80% and a predictive value of 92% for patients with significant coronary artery disease. Treadmill exercise test variables consisting of 2 mm or greater ST depression, downsloping in configuration, lasting more than seven minutes and associated with an abnormal blood pressure response had a sensitivity of 48% and a predictive value of 90% for either left main or three vessel coronary artery disease and a sensitivity of 67% and a predictive value of 48% for left main coronary artery disease.

Bruce treadmill exercise testing and Thallium-201 scanning can identify patients with coronary artery disease and certain combined exercise test variables can aid in determining severe coronary artery disease (left main or three vessel).

Introduction

Exercise stress testing has become a widely used method for evaluating the presence of coronary artery disease. More recently, it has been shown that the addition of Thallium-201 scanning can improve the accuracy of this test.[1,2] Since not only the detection of the presence of coronary artery disease determines the therapy utilized, attempts have now been made to determine the severity of the disease. Recent studies have shown that survival can be improved in certain groups of patients with coronary artery bypass grafting.[3-10]

This study was carried out to determine 1) if treadmill exercise testing and Thallium-201 scanning can accurately identify patients with coronary artery disease and 2) if certain exercise test variables can aid in the detection of severe coronary artery disease (i.e., left main or three vessel disease).

Materials and Methods

Patients

A group of 109 consecutive patients being evaluated for known or suspected ischemic heart disease had treadmill exercise stress tests, Thallium-201 scanning and cardiac catheterization. Clinical features analyzed included age, sex, type of chest pain, and presence or absence of prior infarction or arrhythmia.

Exercise Test

All patients underwent treadmill exercise testing according to the standard Bruce protocol.[11] A twelve lead electrocardiogram and blood pressure were recorded at rest, monitored during exercise and again recorded in the recovery period until chest pain, ST changes and arrhythmia resolved.

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Thallium-201 Scan

Each patient also had a 2 mCi dose of Thallium-201 injected at peak exercise by an established intravenous route, and continued to exercise for 30-60 seconds. Using a scintillation camera imaging was begun within 2-5 minutes in anterior, 45° left anterior oblique and lateral views. Reperfusion images were obtained at 4 hours.

Coronary Arteriography

Coronary arteriography was obtained using either standard femoral[12] or brachial[13] routes and recorded in multiple views. For the analysis of the coronary angiogram significant coronary stenosis was judged by the presence of a 50 per cent or greater reduction in vessel diameter.

Exclusions

From the initial 109 patients those excluded included 16 patients unable to achieve 85% of the age adjusted maximal heart rate; 2 patients with valvular heart disease and 2 patients with left bundle branch block.

Variables Analyzed

The variables of the treadmill test that were analyzed included total treadmill time, S-T segment response (configuration, degree of depression in mm, location, and duration for recovery), R wave response, blood pressure response, double product (heart rate x blood pressure), symptoms limiting exercise and arrhythmias.

Patient Groups

Of the 89 patients studied on the basis of their coronary anatomy five groups were defined. Group I $(n = 15)$ included all patients with left main coronary artery disease with or without other vessel involvement. Group II $(n = 25)$ included all patients with three vessel coronary artery disease, excluding those with left main coronary artery disease. Group III $(n = 40)$ included all patients with severe coronary artery disease, left main and/or three vessel coronary artery disease (Group I and Group II). Group IV included all patients with single and double vessel coronary artery disease and these were subdivided. Group V included all patients without significant coronary artery disease.

Definitions

For analysis of treadmill exercise test and Thallium scan data the following formulae were used:

$$\text{Sensitivity} = \begin{array}{l}\text{\% with}\\ \text{disease and}\\ \text{positive test}\end{array} = \frac{\text{true}(+)}{\text{true}(+) + \text{false}(-)} \times 100$$

$$\text{Specificity} = \begin{array}{l}\text{\% of normals}\\ \text{with negative}\\ \text{tests}\end{array} = \frac{\text{true}(-)}{\text{false}(+) + \text{true}(-)} \times 100$$

$$\begin{array}{c}\text{Predictive}\\ \text{Value}\end{array} = \begin{array}{l}\text{\% of patients}\\ \text{with abnormal}\\ \text{tests who}\\ \text{have disease}\end{array} = \frac{\text{true}(+)}{\text{true}(+) + \text{false}(+)} \times 100$$

For analysis of exercise test variables the following formulae were used: Sensitivity (per cent) was calculated by dividing the abnormal variable of any single group by all patients in that group and multiplying by 100. Predictive value (per cent) was calculated by dividing all patients in the group analyzed with the abnormal variable by all patients with the abnormal variable and multiplying by 100.[14]

Results

Clinical Characteristics (Table 1.)

Of the 89 patients, 15 had left main coronary artery disease, 25 had three vessel coronary artery disease, 24 had single and double vessel coronary artery disease and 25 were normal. From a clinical viewpoint the groups with coronary artery disease could not be differentiated from one another. However, in the patients with coronary artery disease the incidence of males was higher, typical angina was more frequent and prior myocardial infarction was found only in these patients.

Table 1

CLINICAL FEATURES AND PRESENTATION OF 89 PATIENTS

	Group I (n=15)	*Group II (n=25)*	*Group III (n=40)*	*Group IV (n=24)*		*Group V (n=25)*
				double (n=14)	*single (n=10)*	
Age (year)						
Range	40-67	34-68	34-68	36-66	34-64	21-62
Average	60	54	56	55	50	48
Sex						
Male	13 (87%)	20 (80%)	33 (83%)	13 (93%)	9 (90%)	10 (40%)
Female	2 (13%)	5 (20%)	7 (17%)	1 (7%)	1 (10%)	15 (60%)
Presentation						
Chest Pain						
typical angina	9 (60%)	4 (16%)	15 (38%)	6 (43%)	4 (40%)	3 (12%)
atypical chest pain		11 (44%)	11 (28%)	2 (15%)	2 (20%)	21 (84%)
Post Infarction						
asymptomatic		4 (16%)	4 (10)%	1 (6%)	3 (30%)	
symptomatic	6 (40%)	5 (20%)	11 (28%)	5 (36%)	1 (10%)	
Arrhythmia		1 (4%)	1 (2%)			1 (4%)

Identification of Patients with Coronary Artery Disease

Comparison of treadmill exercise testing with Thallium-201 scanning and coronary arteriography is shown in Table 2 and Table 3. In identifying patients with coronary artery disease no attempt was made to examine variables of either the treadmill exercise test or the Thallium-201 scan other than their positivity or negativity. Although each test by itself achieves similar sensitivity and predictive values, the specificity is enhanced by requiring that both tests be positive (i.e. abnormal) without compromising either sensitivity or predictive value. It is important to note that 5 patients who had a false positive thallium scan had mitral valve prolapse.

Table 2

COMPARISON OF TREADMILL EXERCISE TEST AND THALLIUM-201 SCAN WITH CORONARY ANGIOGRAPHY

	Coronary Angiography	
	Positive	*Negative*
Thallium-201 Scan		
Positive	59 T+	8 F+
Negative	5 F−	17 T−
Treadmill Exercise Test		
Positive	63 T+	11 F+
Negative	1 F−	14 T−
Treadmill Test + thallium-201 Scan		
Both Positive	58 T+	5 F+
Both Negative	6 F−	20 T−

T+ = true positive; F+ = false positive;
T− = true negative; F− = false negative

Table 3

COMPARATIVE RESULTS

	Treadmill Exercise Test %	*Thallium-201 Scan* %	*Thallium-201 Scan and Treadmill Exercise Test* %
Sensitivity	98	92	90
Specificity	56	68	80
Predictive Value	85	88	92

Determination of Severity of Coronary Artery Disease

Analysis of Characteristics in Table 4.

The total treadmill time was not helpful in differentiating any groups of patients. The analysis of the ST response was helpful in many respects. Those patients with severe disease (group III) had a statistically

Table 4

CHARACTERISTICS OF TREADMILL EXERCISE TEST

	Group I (n=15)	*Group II (n=25)*	*Group III (n=40)*	*Group IV (n=24)*		*Group V (n=25)*
				double (n=14)	*single (n=10)*	
Bruce Treadmill Time						
Stage I .0 - 1.5 min.				1 (8%)		
1.5 - 3.0 min.	5 (33%)	4 (16%)	9 (22%)	2 (14%)	1 (10%)	3 (12%)
Stage II 3.0 - 4.5 min.	2 (13%)	5 (20%)	7 (18%)	3 (22%)		1 (4%) **
4.5 - 6.0 min.	6 (40%)	7 (28%)	13 (32%)	4 (28%)	3 (30%)	1 (4%) **
Stage III 6.0 - 7.5 min.	1 (7%)	4 (16%)	5 (13%)	2 (14%)	2 (20%)	5 (20%)
7.5 - 9.0 min.				2 (14%)	3 (30%) **	8 (32%) **
Stage IV 9.0 - 10.5 min.		3 (12%)	3 (8%)		1 (10%)	3 (12%)
10.5 - 12.0 min.	1 (7%)	2 (8%)	3 (8%)			4 (16%) **
ST Response						
Configuration						
upsloping	0	0	0	2 (14%)	3 (30%) *	3 (12%)
horizontal	3 (20%)	10 (40%)	13 (32%)	7 (50%)	4 (40%)	7 (28%)
downsloping	12 (80%)	15 (60%)	27 (68%)	5 (36%) **	2 (20%) **	1 (4%) **
Degree						
0 < 1 mm.					1 (10%)	14 (56%) **
> 1 < 2 mm.	2 (13%)	5 (20%)	7 (18%)	8 (58%) **	7 (70%) **	10 (40%) *
> 2 < 3 mm.	5 (33%)	12 (48%)	17 (42%)	4 (28%)	2 (20%)	1 (4%) **
> 3	8 (54%)	8 (32%)	16 (40%)	2 (14%) *		
Greater than Number of Abnormal Locations						
one	2 (13%)	11 (44%)	13 (32%)	7 (50%) **	6 (60%) **	3 (12%) **
two	11 (74%)	13 (52%)	24 (60%)	7 (50%)	3 (30%)	8 (32%)
three	2 (13%)	1 (4%)	3 (8%)			
Duration						
< 7 min.	3 (20%)	6 (24%)	9 (22%)	6 (44%)	7 (70%) **	4 (16%) *
7 - 10 min.	5 (33%)	6 (24%)	11 (28%)	4 (28%)	2 (20%)	3 (12%)
11 - 15 min.	6 (40%)	13 (52%)	19 (48%)	4 (28%) **		4 (16%) **
> 15 min.	1 (7%)		1 (2%)			
Abnormal R wave Response V_4-V_6	9 (60%)	10 (40%)	19 (48%)	4 (28%)	5 (50%)	3 (12%) **

* $p < 0.05$ when compared to group III
** $p < 0.01$ when compared to group III

significant increase in frequency of downsloping ST depression and a greater degree of ST depression (greater than 3 mm) when compared to group IV. The number of locations where ST depression occurred was grouped as inferior (II, III, aVF); anterior (V_1-V_3); and lateral (V_4-V_6) and quantitated as one, two, or three locations. Only group III patients had ST depression in three locations. The duration of the abnormal ST segment response for group III patients was longer, lasting greater than 7 minutes in 78% of these patients but being statistically significant only when greater than 11 minutes. An abnormal R wave response was not useful in differentiating groups.

Analysis of Characteristics in Table 5.

An abnormal blood pressure response (no rise or fall) was statistically significant in differentiating group III from group IV patients (68% incidence vs. 28% incidence respectively). Evaluation of the double product at peak exercise, the symptom limiting exercise, and benign arrhythmias were not helpful in differentiating groups. Ventricular tachycardia occurred only in group III patients but this represented only 8% of the group.

Sensitivity and Predictive Value of Exercise Test Variables (Table 6.)

Individual Variables: When analyzing the ST segment response, 2 mm ST depression, downsloping configuration, a duration of greater than 7 minutes, and an abnormal blood pressure response achieved the best sensitivity and predictive value for identifying severe disease (group III) but could not differentiate group I from group II. Chest pain, the peak double product during stress, and clinical features were as sensitive but their predictive value was much lower.

Combined Variables: When all patients were analyzed for the combined presence of 2 mm or more ST depression, downsloping in configuration, lasting more than 7 minutes and associated with an abnormal blood pressure response, this resulted in a sensitivity of 48% and predictive value of 90% for either left main or three vessel coronary artery disease and a sensitivity of 67% and a predictive value of 48% for left main coronary artery disease.

Discussion

The identification of the presence and severity of coronary artery disease is a frequently encountered diagnostic problem in clinical medicine today. As more and improved therapeutic interventions become available (both medical and surgical) improvement in diagnosis results in improved prognosis. The initial approach to this disease remains clinical and all patients referred for further evaluation will reflect this initial triage. It has become evident that regardless of the laboratory test employed, its ability to detect disease is dependent on the population that is analyzed.[15] The 89

Table 5

CHARACTERISTICS OF TREADMILL EXERCISE TEST

	Group I (n=15)	*Group II (n=25)*	*Group III (n=40)*	*Group IV (n=24)*		*Group V (n=25)*
				double (n=14)	*single (n=10)*	
Systolic Blood Pressure Response						
Normal	4 (27%)	9 (36%)	13 (32%)	10 (72%) **	10 (100%) **	23 (92%) **
No Rise	2 (13%)	1 (4%)	3 (8%)	2 (14%)		1 (4%)
< 10 mm Drop		5 (20%)	5 (12%)	1 (7%)		
10 - 19 Drop	3 (20%)	8 (32%)	11 (28%)	1 (7%) *		1 (4%) *
20 - 29 Drop	4 (27%)	1 (4%)	5 (12%)			
30 - 39 Drop						
40 - 49 Drop	2 (13%)	1 (4%)	3 (8%)			
Double Product (HR x BP) ÷ 10^2						
< 150	8 (53%)	4 (26%)	12 (30%)	3 (21%)	1 (10%)	3 (12%)
150-199	5 (33%)	9 (36%)	14 (35%)	5 (37%)	2 (20%)	3 (12%)*
200-249	2 (14%)	6 (24%)	8 (20%)	3 (21%)	2 (20%)	9 (36%)
250-299		5 (20%)	5 (13%)	3 (21%)	3 (30%)	5 (20%)
300-349		1 (4%)	1 (2%)		2 (20%)	2 (8%)
350-399						2 (8%)
> 400						1 (4%)
Symptom Limiting Exercise						
Chest Pain	10 (66%)	15 (60%)	25 (62%)	7 (50%)	5 (20%)	2 (8%) **
Shortness of Breath	4 (27%)	6 (24%)	10 (25%)	5 (30%)	2 (20%)	6 (24%)
Dizziness				2 (14%)		
Arrhythmia		3 (12%)	3 (8%)		2 (20%)	
Fatigue	1 (7%)	1 (4%)	2 (5%)		1 (10%)	17 (68%) *
Arrhythmia During Exercise						
Atrial (PACs or SVT)	1 (7%)	1 (4%)	2 (5%)	1 (6%)	1 (10%)	
Ventricular (PVCs)	4 (26%)	9 (36%)	13 (32%)	6 (44%)	4 (40%)	5 (20%)
Ventricular tachycardia	1 (7%)	2 (8%)	3 (8%)			

* $p < 0.05$ when compared to group III

** $p < 0.01$ when compared to group III

Table 6

SENSITIVITY AND PREDICTIVE VALUE OF INDIVIDUAL CLINICAL AND EXERCISE TEST VARIABLES FOR THE DETECTION OF LEFT MAIN (group I), THREE VESSEL (group II) AND LEFT MAIN OR THREE VESSEL CORONARY DISEASE (group III)

	Group I		*Group II*		*Group III*	
	Sensitivity %	*Predictive Value %*	*Sensitivity %*	*Predictive Value %*	*Sensitivity %*	*Predictive Value %*
Stress Test						
ST Depression						
Amount						
$\geq$ 2 mm	87	31	80	48	83	79
$\geq$ 3 mm	53	44	32	44	40	89
Configuration						
horizontal	20	10	40	32	32	42
downsloping	80	34	60	43	68	77
Duration						
> 7 minutes	80	25	76	40	78	65
Blood Pressure Response						
Abnormal	73	33	64	48	68	82
Chest Pain						
Presence	66	26	60	38	62	64
Double Product (HR x BP) ÷ 10^2						
< 200	87	30	52	30	65	60
Clinical Features						
Age 50 years	87	23	68	30	75	54
Male	87	20	80	31	83	51
Typical Angina	100	35	36	21	50	47
Prior Infarction	40	30	32	40	35	70

patients in this study therefore reflect this clinical process in that all were suspected or known to have ischemic heart disease by some clinical characteristic. A further decision-making process resulted in them having a diagnostic "gold standard" performed (i.e. coronary arteriography). These patients therefore represent a "selected" group in that at no time did a clinical characteristic, stress exercise test, or thallium scan result automatically require as part of a protocol that coronary arteriography be performed.

The correlation of results of stress exercise testing with coronary arteriography depends on: the criteria used to define a positive test; the population studied;[16] and the presence of abnormalities on the resting electrocardiogram.[17-20] Our results show a high degree of sensitivity (98%) because our criteria for a positive stress test was defined as 1 mm of ST depression.[21] This however results in a specificity of only 56%.

The combination of stress testing with thallium scanning has resulted in increased specificity without appreciable change in sensitivity.[1,2] Using this combined method our specificity can be increased to 80%. Therefore in appropriately selected patients results of stress exercise testing and thallium scanning can be very useful in identifying patients with coronary artery disease. These results would obviously not apply to asymptomatic patients[22] in whom there is no reason to suspect coronary artery disease.

There is evidence now that patients with severe coronary artery disease: left main[3-6] and triple vessel[7-10] will benefit by prolongation of life with coronary artery bypass surgery. For this reason several stress test variables were analyzed in an attempt to identify these patients.

In this regard the precise configuration of the ST segment, the degree of ST depression,[23] the time of appearance and the duration of the ST segment abnormalities have refined the accuracy of the test.[24-26] Ventricular arrhythmias have also been helpful in identifying high risk subjects.[27-29] Hypotension[30-33] or a significant drop in blood pressure[34] have been strong modifiers indicating severe disease as well as the duration of ischemic response persisting long into the recovery phase.[24]

It has been shown that combining variables can increase predictive value of severe disease.[24] A marked ischemic response and an abnormal blood pressure response have been shown to be sensitive and predictive of severe disease.[35] A combination of 2 mm ST depression, downsloping, starting in Stage I, lasting at least 6 minutes and displayed in five leads was shown to be predictive and sensitive by Weiner et al.[14]

Our results indicate that a combination of 2 mm of ST depression, downsloping in configuration, lasting more than 7 minutes and associated with an abnormal blood pressure response has a sensitivity of 48% and a predictive value of 90% for either left main or three vessel disease and a sensitivity of 67% and a predictive value of 48% for left main coronary artery disease.

The results of our study support the views that: 1) in selected populations stress testing can be sensitive in detecting coronary artery disease; 2) Thallium-201 scanning can enhance the specificity; and 3) combinations of stress test variables can be used to identify patients with severe coronary artery disease and allow stress testing to be regarded as semiquantitative.

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Thrombolytic Therapy in Thrombosis

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Assisted by the Office for Medical Applications of Research, NIH

Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A National Institutes of Health Consensus Development Conference, held at NIH April 10-12, 1980, addressed the issue of thrombolytic therapy* for the management of acute deep-vein thrombosis and pulmonary embolism.

At NIH, consensus development conferences bring together biomedical research scientists, practicing physicians, consumers, and others as appropriate in an effort to reach general agreement on the safety and effectiveness of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

A consensus development panel, after listening to expert presentations at the NIH conference on Thrombolytic Therapy in Thrombosis, issued the following consensus statement:

For over three decades, the primary method of therapy used by almost all physicians for the management of acute deep-vein thrombosis and pulmonary embolism has been anticoagulation. This form of therapy has become so ingrained in medical practice that physicians, while still concerned over the bleeding risk associated with the use of anticoagulants, nevertheless seem secure in the belief that they are providing optimal, if not ideal, therapy for these disorders. With the advent of thrombolytic therapy, this is no longer true for a large number of cases. Anticoagulation for the management of acute deep-vein thrombosis and pulmonary embolism, while usually effective in preventing or slowing further thrombus formation in veins and significantly diminishing the likelihood of subsequent or recurrent embolization, does *not:*

- eliminate the source of subsequent embolization in the deep veins during the acute attack;
- alleviate the hemodynamic disturbances associated with the thrombosis or embolism;
- prevent subsequent valvular damage to the deep veins and the development of persistent venous hypertension and associated symptomatology in the lower extremities which may predispose to recurrent deep-vein thrombosis and pulmonary embolism; and
- prevent permanent impairment to the pulmonary vascular bed and, in patients with more extensive involvement, persistence of pulmonary hypertension.

The reason that patients with acute deep-vein thrombosis and pulmonary embolism treated with anticoagulation alone are subject to these complications is that such therapy has no acute effect on previously formed thrombi or emboli. Its role is primarily that of secondary intervention, i.e., prophylaxis against further thrombus growth, recurrence and embolization. The natural history of underlying thrombi and emboli treated with anticoagulation alone is mainly one of organization and recanalization.

From these considerations it is apparent that ideal therapy for acute deep-vein thrombosis and pulmonary

*The thrombolytic agents considered at this consensus development conference were urokinase and streptokinase.

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EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

embolism requires either the surgical removal or lysis of the thrombus or embolus so as to restore to normal the hemodynamics and integrity of the vasculature, and the subsequent prevention of recurrence of thrombosis. On the basis of present experience, a surgical approach is usually unsuccessful except under very limited conditions.

However, the lysis of thrombi and emboli can be successfully accomplished in a large number of patients through the proper use of thrombolytic agents. When used in conjunction with anticoagulants, thrombolytic therapy can achieve the objectives of ideal management as follows:

- lyse thrombi and emboli and restore the circulation to normal,
- normalize the hemodynamic disturbances and reduce morbidity,
- prevent venous valvular damage and subsequent venous hypertension in the lower extremities, and
- prevent permanent damage to the pulmonary vascular bed and reduce the likelihood of persisting pulmonary hypertension.

While there are compelling reasons to use this new form of therapy in the management of acute deep-vein thrombosis and pulmonary embolism, it must be recognized that there are risks associated with the use of thrombolytic therapy. Therefore, the administration of thrombolytic agents should be encouraged only in those situations where the benefits to be achieved outweigh the hazards involved. At present this would be for those patients who are suffering from proximal deep-vein thrombosis, i.e., thrombosis involving the popliteal vein or the deep veins of the thigh and pelvis and for those with pulmonary emboli with significant hemodynamic disturbances or where there has been obstruction of blood flow to a lobe or multiple segments providing:

- the diagnosis is established;
- the severity of the clinical problem exceeds the risk of bleeding associated with a major contraindication;
- proper care is taken in the handling of the patient and in the avoidance of any but absolutely essential invasive procedures; and
- there is a clear understanding of the details of therapy including monitoring, management of bleeding complications, and the control of subsequent anticoagulation.

When properly used, in tandem with anticoagulation, thrombolytic therapy as currently practiced represents a significant advance in the management of proximal acute deep-vein thrombosis and the more severe forms of pulmonary embolism. With further developments aimed at improving its efficacy and reducing the bleeding risk, this form of therapy could become the initial treatment for all forms of acute deep-vein thrombosis and pulmonary embolism.

This consensus statement was arrived at following discussion of a series of questions.

I. Are there proven benefits for the use of thrombolytic therapy in currently approved indications, i.e., the more severe forms of acute deep-vein thrombosis and pulmonary embolism?

There are proven benefits as follows:

- Thrombolytic therapy lyses thrombi in the deep venous system and emboli in the pulmonary circulation, and the thrombi and emboli disappear more rapidly than with heparin therapy. These observations are based upon a number of controlled clinical trials in which treatment efficacy was assessed by objective means such as serial pulmonary angiography, perfusion lung scanning and contrast venography.
- Thrombolytic therapy results in a greater improvement or normalization of the abnormal hemodynamic responses to pulmonary embolization than is observed with heparin therapy. These observations are based upon serial studies of selected hemodynamic measurements from the right heart and pulmonary circulation. It has also been shown that lessening of pulmonary hypertension may be observed as early as one and a half hours following initiation of thrombolytic therapy, reaching a maximum in approximately six hours.
- Thrombolytic therapy helps to prevent venous valvular damage and subsequent venous hypertension in the extremities by rapid and more complete lysis of thrombi. It has been demonstrated that patients treated with thrombolytic therapy have a much higher frequency of maintenance of intact and functioning venous valves than do patients treated with heparin alone.
- Thrombolytic therapy may prevent permanent damage to the pulmonary vascular bed by lysing emboli and restoring the pulmonary circulation to normal. In contrast, it has been observed that residual emboli usually persist in patients treated with heparin alone. The presence of such residual emboli, especially significant in those suffering recurrent pulmonary embolism, may result in persistent pulmonary hypertension.

II. What are the risks associated with the use of thrombolytic agents?

Review of the literature indicates that of the undesirable effects associated with current thrombolytic therapy, bleeding poses the major potential risk.

The bleeding associated with thrombolytic therapy is more frequent than with conventional anticoagulants, but this is primarily related to bleeding from sites of invasive procedures. The type of bleeding observed in association with thrombolytic agents can be placed into two broad categories:

- Superficial or surface bleeding, observed mainly at invaded or disturbed sites (e.g.: venous cutdowns, arterial punctures, sites of recent surgical intervention, etc.). This type of bleeding is inherent in the nature of thrombolytic therapy since the use of thrombolytic agents is predicated on their ability to lyse fibrin. One can minimize bleeding at these sites by appropriate patient management and avoidance of procedures that disturb the integrity of the vascular system.
- Internal bleeding observed in the gastrointestinal tract, genitourinary tract, vagina, intramuscular, retroperitoneal, intracerebral, etc. Although this type of bleeding occasionally happens during thrombolytic therapy with a recognizable incidence, it is not statistically different from the incidence of bleeding seen with conventional anticoagulants. However, there is an approximate 1 percent incidence of cerebral hemorrhage associated with thrombolytic therapy compared with a 0.5 percent incidence observed with heparin.

With the utilization of good clinical judgment many of these bleeding problems can be avoided by appropriate case selection and management.

Additional undesirable effects that have been observed in association with thrombolytic therapy include fever and allergic reactions. These occur at a low frequency, are mild, and seldom result in any physiologic injury or the need to discontinue therapy. Anaphylactoid reactions observed with older preparations no longer in use are very rarely observed with the presently employed agents. When such reactions have been observed they uniformly respond to conventional therapy.

III. What are the guidelines for patient selection?

Selection of patients for thrombolytic therapy should be based on the following considerations:

The presence of an appropriate clinical indication including a documented diagnosis and evidence that the thrombus is of recent origin ($\leqslant$ 7 days).

Careful evaluation of contraindications which include the following:

A. Absolute

- Active internal bleeding
- Recent (within two months) cerebrovascular accident or other active intracranial process. There is evidence that currently used thrombolytic regimens carry the hazard of inducing cerebral hemorrhage in those with a recent history of stroke. (However, studies are currently under way using lower agent dosage for the treatment of stroke.)

B. Relative

- Major
  - —Recent (< 10 days) major surgery, obstetrical delivery, organ biopsy, previous puncture of noncompressible vessels
  - —Recent serious GI bleeding
  - —Recent serious trauma
  - —Severe arterial hypertension ($\geqslant$200 systolic or $\geqslant$ 110 diastolic)
- Minor
  - —Recent minor trauma including cardio-pulmonary resuscitation
  - —High likelihood of a left heart thrombus, e.g., mitral disease with atrial fibrillation
  - —Bacterial endocarditis
  - —Hemostatic defects including those associated with severe hepatic or renal disease
  - —Pregnancy
  - —Age > 75 years
  - —Diabetic hemorrhagic retinopathy

IV. Assuming there are proven benefits and a favorable risk/benefit ratio, why are these drugs not being used more frequently?

The panel agreed that while some rationales for deciding against the use of thrombolytic agents were reasonable, such as an inadequate clinical indication or the risk of serious hemorrhage, others were unreasonable. These unreasonable rationales are partly the result of reports of the large multicentered Urokinase and Streptokinase Pulmonary Embolism Trials with their complex biochemical and physiologic studies that required many invasive procedures, and also of the early experience using thrombolytic agents that were less pure than current products and which caused more frequent pyrogenic and allergenic side effects. The unreasonable rationales include the following:

- Fear of bleeding. The Urokinase and Streptokinase Pulmonary Embolism Trials showed a high incidence of bleeding both with thrombolytic agents *and* with heparin. However, the incidence of significant bleeding was only 9 percent for urokinase/streptokinase and 4 percent for heparin. The incidence of major bleeding complications with lytic agents during recent clinical experience, i.e., since the drugs have been available for general physician use, has been about 5 percent. This is based on the patient treatment forms returned to pharmaceutical manufacturers during the continuing surveillance period requested by the Bureau of Biologics, Food and Drug Administration.
- Need for additional invasive procedures. The diagnostic procedures required for thrombolytic therapy are no different from those required for heparin. Objective diagnostic procedures are required for both.

- Confusion regarding dose regulation. There are many directives suggested by the package insert and the general literature that are complex and confusing. For instance, increasing the dose of streptokinase in order to decrease the proteolytic effect is scientifically accurate, but is unnecessary with a fixed dose schedule. Additionally, the streptokinase resistance test is unnecessary, given the 90 percent expectation of inducing a lytic state by the standard loading dose followed by a fixed dose schedule. Altering or eliminating such directives in the package insert would simplify treatment.
- Limited availability of laboratory assays. Although research studies utilized many highly sophisticated assays for following thrombolytic treatment, any one of a number of assays can now be utilized to reflect the circulating "lytic state," the simplest of which is the thrombin time. Whatever the choice of the physician (plasminogen, lysis time, prothrombin time, APTT, FDP's, fibrinogen, etc.) at least one of these assays will be available for use by the practitioner in any hospital laboratory.
- "Evaluate response to heparin first." Any delay in instituting lytic therapy in order to determine whether heparin achieves an initial good response will decrease the potential for optimal response. Therefore, therapy with urokinase or streptokinase should not be deferred after the diagnosis has been established for any reason other than the presence of a serious contraindication to use.
- Decision by committee. The decision to treat need not be made by a committee; such a decision may be made by an informed clinician who is prepared to manage such a patient with a lytic agent.

V. What are the guidelines for patient management and monitoring?

- The diagnosis should be established with objective techniques. If pulmonary angiography is performed the upper extremity should be utilized.
- Before thrombolytic infusion, the following laboratory tests are indicated: A thrombin time (TT), activated partial thromboplastin time (APTT), prothrombin time (PT), hematocrit value and platelet count. If heparin has been given, it should be discontinued and the TT or APTT should be less than twice the normal control value before thrombolytic therapy is started.
- Begin the thrombolytic infusion. During therapy there should not be any invasive procedures performed with the exception of careful venepuncture with a 22 or 23 gauge needle for therapeutic monitoring. If essential, arterial blood gas studies can be performed (upper extremity) but digital compression of the puncture site for at least 30 minutes is mandatory. The patient should be at strict bed rest and pressure dressings applied to previously invaded sites. No new medication should be added to the therapeutic regimen unless absolutely essential. No medication should be added to the bottle containing the thrombolytic agent.
- Vital signs: pulse, temperature, respiratory rate and blood pressure should be performed every four hours during infusion. To avoid dislodgement of deep-vein thrombi the blood pressure should not be taken in the lower extremities.
- Therapeutic monitoring should be performed by utilizing the thrombin time or activated partial thromboplastin time (if neither is available the prothrombin time can be employed). This should be performed at 3-4 hours after institution of the thrombolytic agent (to identify and confirm activation of the fibrinolytic system). Opinions differ regarding the frequency of additional monitoring and its usefulness in predicting or controlling clinical efficacy and bleeding complications. When the TT or APTT is performed a simultaneous hematocrit value is recommenced.
- Should uncontrollable bleeding commence, the thrombolytic infusion should be discontinued and, if necessary, blood loss and reversal of the bleeding tendency can be effectively managed with whole blood (fresh blood preferable), packed red blood cells and cryoprecipitate or frozen plasma.
- Following completion of the thrombolytic infusion, which will vary in duration according to the agent used and the type of the lesion being treated, e.g., deep-vein thrombosis or pulmonary embolism (see package insert for details), the patient should be placed on anticoagulants. After an interval of 3-4 hours following discontinuation of the thrombolytic agent, the TT or the APTT should be performed. When the results of this test no longer exceed twice the normal control value, heparin, without a loading dose, should be instituted and controlled according to standard procedures. This should then be followed by warfarin in the conventional manner.

VI. What are the economic aspects involved in thrombolytic therapy?

The thrombolytic agents available at present, streptokinase and urokinase, are expensive drugs, especially the latter, and their use in patients with venous thrombosis or pulmonary embolism increases the cost of management of the acute thrombotic event. On the other hand, the economic burden imposed on society by the late morbidity of proximal venous thrombosis may be relieved by more widespread use of thrombolytic therapy, which under optimal circumstances restores venous patency and valvular function and prevents the subsequent development of the postphlebitic syndrome. Patients with phlebographic demonstration of complete lysis of proximal venous thrombi by thrombolytic treatment are spared the usual sequelae of venous stasis and their associated costs, which have been estimated at a total of nearly $40,000 per patient over a ten-year period, in severe cases. The frequency of post-thrombotic sequelae in patients with thrombi in the popliteal, femoral, or iliac veins is sufficiently high to make thrombolytic therapy cost-effective in this patient group.

In pulmonary embolism, analysis of cost/benefit ratio is more difficult, for no monetary value has been assigned to the late benefits of improved pulmonary capillary flow and freedom from pulmonary hypertension that appear to follow the use of thrombolytic agents. Analysis of the economic aspects of this issue awaits further data.

VII. What should be the direction for future clinical research?

During the first day of the conference, the basic biochemistry of the fibrinolytic system as it relates to thrombolytic agents was reviewed. The highlights of this session included a discussion of the following: 1) specific activators of plasminogen, including high and low molecular weight urokinase; 2) the mechanism of action of streptokinase-plasminogen complex as a plasminogen activator; 3) the physiological activators of plasminogen; 4) natural inhibitors of plasmin and urokinase, including the kinetics of inhibition of plasmin by α_2 antiplasmin; 5) the clinical manifestations of a patient with an abnormal plasminogen which resulted in a thrombotic tendency; 6) the use of synthetic substrates for assessment of various components of the fibrinolytic system; and 7) the detailed biochemical characterization of glu and lys plasminogen. Mechanisms of in vivo fibrinolysis were reviewed. In addition, a newly identified plasma protein (histidine rich glycoprotein), which has the capacity to block the binding of plasminogen to fibrin, was reported. Preliminary data suggested that human tissue activator of plasminogen was a more selective activator of fibrinolysis than urokinase.

On the basis of the foregoing, the possible therapeutic role of new thrombolytic agents should be evaluated, such as SK-plasminogen complex, activators of tissue origin, B chain-SK complex and the like.

There is also a need for further evaluation of current tests in terms of predicting thrombolytic success and bleeding. In addition, simple and practical tests reflecting or indicative of fibrin (thrombus) dissolution are highly desirable and would be a substantial contribution to further progress in this field.

Further clinical research is also required to evaluate the effects of different regimens involving dosage, durations and combinations with other agents, e.g., plasminogen and heparin. More information is needed on the efficacy and diminished risk of bleeding when SK or UK is administered regionally rather than systemically. Investigations should also be encouraged for other indications of thrombolysis, including acute myocardial infarction.

This Consensus Conference on Thrombolytic Therapy in Thrombosis was sponsored by the National Heart, Lung, and Blood Institute in collaboration with the Food and Drug Administration, with the assistance of the Office for Medical Applications of Research, Office of the Director, NIH.

Members of the Consensus Development Panel were Dr. Sol Sherry, Temple University School of Medicine, Philadelphia, Pennsylvania (Chairman); Dr. William R. Bell, The Johns Hopkins University School of Medicine, Baltimore, Maryland; Dr. F.H. Duckert, Katonsspital, Basel, Switzerland; Dr. Anthony P. Fletcher, Washington University School of Medicine, St. Louis, Missouri; Dr. Victor Gurewich, St. Elizabeth's Hospital, Boston, Massachusetts; Dr. David M. Long, La Mesa, California; Dr. Victor J. Marder, The University of Rochester, Rochester, New York; Dr. Harold Roberts, University of North Carolina, Chapel Hill, North Carolina; Dr. Edwin W. Salzman, Beth Israel Hospital, Boston, Massachusetts; Dr. Arthur Sasahara, Veterans Administration Hospital, West Roxbury, Massachusetts; Dr. Marc Verstraete, University of Leuven, Leuven, Belgium.

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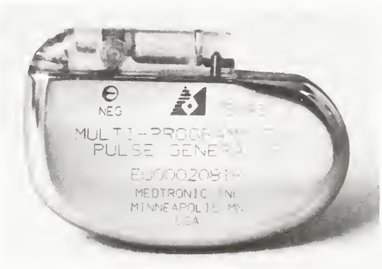

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The Entry of Microbiology into Clinical Medicine

STEVEN C. GREENBERG

> *LISTER can never pass out of the world's memory. Though dead, he still goes on healing. He is one of our Immortals, and, in years to come, the generations yet unborn will regard him as one of the greatest benefactors of mankind and will recognize the injustice of the simile that has likened him to Aaron of old, who stood in the day of pestilence between the dead and the living, for by Lister, and Lister alone, the Plague of Surgical Sepsis was stayed. Of this it is well to be reminded from time to time—"Lest we forget."*
>
> —George Thos. Beatson

As medical research focuses on the complexities of the cell in an attempt to conquer further frontiers, it is easy to lose sight of the pioneering efforts that brought us to this era. The brilliant contribution of Louis Pasteur and its ingenious application by Joseph Lister catapulted the capabilities of medicine and surgery. The work of these two men marks the cornerstone for the entry of microbiology into clinical medicine; it represents genius seen only in rare circumstance.

It was approximately the mid 19th century when the overlapping careers of Pasteur and Lister revolutionized medicine. In Lille, 1866, Pasteur (then Professor and Dean of the Faculté des Sciences) was approached by the local wine manufacturers, who were in difficulty with their production of beetroot alcohol. With the prospect of promoting the name of his new school and of aiding in the production of wine by the community manufacturers, Pasteur took upon himself the study of the fermentation process. In his keen observations with the microscope, he noted differences in fermented beetroot juice with and without filtration. Globules were seen in the healthy ferment that had never before been reported. They were small, arranged in zones, and within the grey substance of the ferment. Previously, Cagniard-Latour had associated the "budding" reproduction of yeast with sugar fermentation. But the globules found by Pasteur were smaller than yeast, and when the ferment was unhealthy, the globules were irregularly elongated.

Such findings provided a new perspective for the theory of fermentation and further impetus for experimentation with "infinitely little animalculae." Fracastorius' 16th century suggestion paralleling fermentation with "contagion" (the transmission of seeds from person to person) would be rediscovered; the theory of spontaneous generation would be disproved. Pasteur showed that the presence of globules in a fermentable liquid was due to exposure to air—without which no alteration was seen.

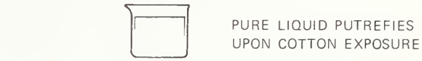
AIR
COTTON
ASPIRATE
EXPOSURE TO AIR TURNS COTTON BLACK
PURE LIQUID PUTREFIES UPON COTTON EXPOSURE

Figure 1

With the conclusion that the fermentation of the liquid solution was due to microbes from the air, these agents of fermentation became known as "infusoria." In subsequent experimentation with other forms of fermentation, Pasteur found that contact between these air-derived infusoria and the fermentable liquid alone could not explain the phenomenon of chemical altera-

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STEVEN C. GREENBERG, University of Connecticut School of Medicine, Class of 1982.

tion. The fermentation of sugar, mannite and lactic acid to butyric acid is due exclusively to infusoria that cannot tolerate air. These "anaerobes" suggested the existence of different forms of animalculae.

To test the hypothesis that fermentation paralleled putrefaction, Pasteur studied organic matter (blood and urine) of a dog. Comparing the alteration of these materials under pure and impure conditions, the conclusion that microbes cause chemical fermentation became applicable to all organic substances. Pasteur conveyed the significance of his experimentation after meeting with Napoleon III, "I assured the emperor that all my ambition was to arrive at the knowledge of the cause of putrid and contagious diseases."

The nature of the cause of disease was the essential question. Prior to Pasteur, the characterization of the disease state was clearly defined in terms of signs, symptoms, prognosis, and treatment. Most treatment was based on irrational theory, and continued to be so until the cause of the disease was found. Pasteur integrated a highly theoretical and pure chemistry background with a practical social concern in France, and prophetically extrapolated his discoveries to this most enigmatic aspect of medical science. In doing so, he left to the clinicians the obligation for application of his principles, by no means an easy task.

The state of mid-19th century clinical medicine underlies the impact of the changes that were to develop. Admittance to the hospital was equated with an extremely poor prognosis. Operations were often fatal, and were suggested only in cases where death was certain without them. Wound treatment by surgeons carried with it unpredictable results. Surgical procedures included air-exclusion by dressings, water-bath irrigation, oxygen gas substitution, and application of salves and lotions. Success was frequently random.

In Glasgow, Joseph Lister was scientifically and clinically involved with the process of wound healing. The frustration in this field was manifested by the likelihood of death from sepsis in any given case. Lister's early laboratory research in coagulation and inflammation led him to conclude that sepsis and putrefaction were correlated. This implied that preventing septic disease would necessarily require preventing the precipitating putrefaction. This was the central issue when Pasteur's work was brought to the attention of Lister. The Glasgow surgeon was then able to give definitive application to the theory of the infusoria. Sepsis could be controlled if in fact putrefaction was a phenomenon brought on by corpuscular matter within the air rather than a gas of the air itself.

Lister's extraordinary commitment to surgical improvement inspired continual innovation in his own practice and teaching. His mere institution of rigorous cleanliness was significant in the success he was to experience. (Previously, a blood-bathed frock marked a surgeon's status, while instruments were simply washed and dried before being stored in the practitioner's pocket.) With the enlightenment of the germ theory, Lister made his most outstanding contribution. Before him, Dr. Jules Lemaire expressed ideas similar to Lister's, but his practical application fell short. Lister was definitive and unyielding in his application of Pasteur's principles. Germs must be prevented from entry into the wound and must be killed within the wound. In Watson-Cheyne's words, "to Lister, no matter was more urgent or might be more fruitful than the attempt to find out the cause, the prevention, and the best methods of treatment of these septic diseases."

The axiom that chance favors the prepared mind was exemplified again by Lister. A news story in Carlisle describing the use of carbolic acid to prevent sewage smell related the coincidental finding of the disappearance of entozoa infestation in their grazing cattle. Lister sought such an agent to initiate his "antiseptic treatment." He began with carbolic gauze and lotion, and later developed his carbolic acid spray, attempting to sterilize not only the area of the wound but also the air around it. The carbolic acid proved successful, but its irritation to healthy tissue and its propensity to obstruct the view of the surgical area induced rigid opposition. Claims were made that Lister's increased success was due to his cleanliness rather than the carbolic acid—that washing his hands alone would decrease the concentration of micrococcus epidermidis enough to significantly better his results. In his 1875 speech opening the Surgical Section of the British Medical Association, Lister speaks of the adverse hospital conditions caused by overcrowding and impracticality of cleaning. "If we take cleanliness in any other sense

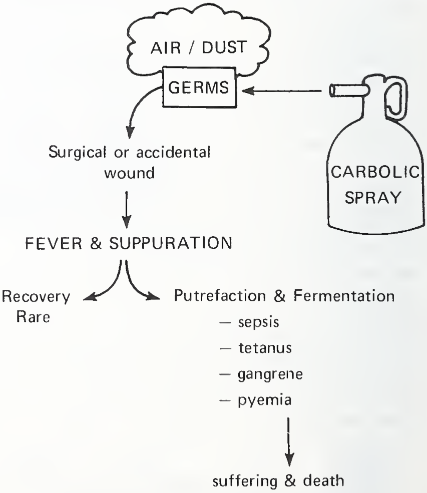

Figure 2

than antiseptic cleanliness, my patients have the dirtiest wounds and sores in the world." Watson-Cheyne comments, "the fight was one which few would have carried out to its end, but Lister's profound conviction of the truth and value of what he was battling, viz., the abolition of sepsis on the lines laid down in his writings, and of the enormous benefit to mankind if the problems were successfully solved, enabled him to put prejudice and ridicule aside and leave the verdict to the future."

Lister sought continual improvement in his method. He experimented with various chemicals on his own arms, seeking a less irritating substitute for carbolic acid. None were found to be as efficacious, but a marked advance was made when chemists were able to dilute from one part carbolic acid in three parts linseed oil to one part carbolic acid in twenty parts water. Irritation and opacity were both diminished without compromising antisepsis.

Lister's antiseptic surgical technique was refined further. His clinical work was experimental, complemented by his laboratory interests. He mixed carbolic acid with blood and produced an aseptic clot with healthy granulation tissue. Lister also developed a protective gauze dressing, testing it with a carbolic acid-pus mixture. Ligatures, sutures, and drains were similarly processed to follow the antiseptic doctrine. Although Listerism was to remain a slowly accepted practice for some time, during a seven year period Lister made surgery a method of prolonging life, limb, usefulness, and comfort to humankind.

The field of microbiology in medicine was markedly advanced through the bacteriological works of Robert Koch and Wm. Watson-Cheyne in the 1880's. Koch gave the first absolute proof of the infectious nature of bacteria. Bacteria were isolated from the infected host and, upon injection into experimental animals, induced similar infection. He thereby demonstrated the role of bacteria in the etiology of wound infections. Watson-Cheyne isolated bacteria from aseptic wounds, initially raising questions concerning the validity of the Pasteur theory. His work proved to be indicative of the bacterial world and the non-pathogenicity of some strains. The realization from this that contact germs (rather than atmospheric) were the organisms of major concern allowed Lister to eliminate the use of the carbolic spray from his practice. Ultimately, the advent of oil immersion lenses, bacterial stains, and solid growth media confirmed the hypotheses set forth by Pasteur and Lister.

The final form of the clinical application of bacteriology was shaped when Lister's "antiseptic" technique was displaced by the "aseptic" method, first introduced by Gustav Neuber, in 1886. Removing chemicals from treatment would obviously eliminate the irritation that had compromised technique since Lister's earliest work. Lister had promulgated the idea of chemical-free antisepsis by the use of cotton-wool filtration. However, this method proved to be tedious and not completely satisfactory. In 1890, heat became the bactericidal mode with the realization that germs of contact (via hands and instruments) were of primary concern. Sterility of instruments, clothing, and accessories was accomplished by autoclave. Masks controlled oral germs. The idea of destroying bacteria gave way to the idea of prophylaxis against bacteria. Although both methods had a common end—the production of a germ-free wound—the means to this end differed in theory and practice.

Our modern conception of medical and surgical bacteriology is derived quite directly from the theories of Pasteur and the clinical practice of Lister. These two men in large measure changed attitudes towards health and lifestyle by furthering the capabilities of the medical profession. The battle between the "contagion" and the body was exposed, fought, and successfully concluded. We can now marvel at the powers of medicine, but not without acknowledgement of the uncompromising devotion of some of the men who were responsible.

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Costs Limitations: Two Federal Approaches

PAUL R. M. DONELAN

Dr. Julius Richmond is the Assistant Secretary for Health, Department of Health, Education and Welfare and the Surgeon General of the Public Health Service. He is the chief medical advisor to the Secretary of HEW. He is responsible for the operation of six (6) major Public Health Services agencies—Alcohol, Drug Abuse, Mental Health Administration, Center for Disease Control, Food and Drug Administration, Health Resources Administration, Health Services Administration, and National Institutes of Health. In one way or another, each of these agencies will affect your practices. As Surgeon General, Julie has been known to autograph cigarette packages.

Dr. Richmond also is responsible for the operations of the Office of the Assistant Secretary of Health. In that office, there are a number of operations which will affect your day-to-day working lives. Thus we introduce you to Mrs. Ruth Hanft and Dr. Seymour Perry.

Mrs. Hanft is the Deputy Assistant Secretary for Health Research, Statistics and Technology. The last area—technology—is one of the areas I want to discuss with you. To tickle your interest, let me point out that Ruth was the primary actor—or actress, as the case may be—who put together the national guidelines under the Health Planning Act that set limits for CT scanners, hospital beds, open heart surgery, etc., in 1977.

Dr. Perry is a physician, formerly with National Institute of Health, who is the Director of the soon-to-be-heard-from National Center for Health Care Technology. He seems to have a genuine concern for the practicing physician, and though his job may be the source of future unhappiness to some physicians, he has the potential for being a moderating influence on some of the wilder elements in HEW.

John Gibbons, Ph.D., is the Director of the Congressional Office of Technology Assessment (OTA). Doctor Joyce Lashoff works with him and is primarily responsible for operations in the health field. She was Dr. Richmond's Deputy Assistant Secretary for Health Programs and was intended to be his principal deputy. She had come into the Federal Government from the state of Illinois. Shortly after her arrival, while Dr. Richmond was in Europe, Secretary Califano designated a layman as the Acting Assistant Secretary. Dr. Lashoff had gumption enough to object and, finding herself unsuccessful, she resigned.

Leonard Schaeffer is the Administrator of the Health Care Financing Administration (HCFA). He has the ultimate responsibility for running the Medicare and Medicaid programs. Even if you do not have patients who are covered under these programs, whatever he does with respect to these programs will affect your practices. When he sets the rules for the operations of Medicare and Medicaid, he, in effect, sets the rules for the entire health field. Let me give you a single illustration.

Two weeks ago, HCFA issued proposed rules to govern hospital reports under Medicare. The reports are called the Annual Hospital Report (AHR). Since Medicare amounts to 1/3 of the average hospital's patient load, hospitals would have to maintain two sets of books. This is impractical. Further, other insurance programs would like to have the same information about services to their beneficiaries and will pressure the hospitals to provide it. Thus, the hospitals will be "inspired" to modify their reporting systems for all their operations.

Now that we have the names of the personnel, let me get to the main subjects of my presentation: regulatory activities under the new Department of Human Services and how these will affect physicians in private practice.

I know I am not telling you anything new when I say costs are the main concern of government in the health field. I may be telling you something new when I say that it did not begin with the Carter Administration. The concept of the so-called Health Maintenance Organization or HMO was seized upon by the Nixon Administration as a cost-saving mechanism in 1968.

Presentation of PAUL R. M. DONELAN, Deputy Director, Washington Office, American Medical Association, recently before Council of New England State Medical Societies, Boston, MA.

PSRO, originally conceived as a mechanism to improve the quality of care, is also viewed as a cost-saving device, although presently its value as a cost-saver is being called into question by the House Appropriations Subcommittee staff.

The Health Planning Act, which despite all its faults, has the potential for determining health needs throughout the country, has been prostituted into a purely cost-saving program. Inflation and the current desire for a balanced budget will exacerbate cost-saving activities.

I shall now discuss two areas which are now under serious exploration, but whose future effects are as yet unknown. These are technology and the Medicaid Management Information System (MMIS).

A few years back, there was much discussion about the CAT scanner. Although there were fewer than 150 scanners throughout the country, they suddenly took on a sinister cast. The fear was that not only would every hospital want a scanner, but that every physician would also. The generator of that fear was the congressional Office of Technology Assessment. I am told that there were some embarrassed smiles at OTA when the developers of the CT scanners were awarded the Nobel Prize recently.

So that you will understand whence OTA is coming, I would like to read a brief description of its Cost-Effectiveness of Medical Technology Project and I quote:

> "Cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) are techniques for aiding decision-making. They are purposeful applications of an organized body of economic and decision theory-related knowledge. A great amount of confusion surrounds their meaning and form, and their use may result in effects on society that go beyond the immediate and intended effects.
>
> "Can CEAs or CBAs enhance the rationality of resource allocation in health care? If so, in which circumstances? Are the resultant data accurate and relevant? Do the 'number' resulting from CEAs influence policy debates or discussions to an extent commensurate with their value, or do they play too large or too small a role? This last question introduces a new level of complexity into the search for appropriate use of CEA and CBA. Their appropriate level of influence in any policy debate should depend not only on the accuracy and relevance of the data they can provide but also, and importantly, on the other factors influencing the debate. These factors may include questions of ethics, equity, income redistribution, public and political needs and desires, administrative feasibility, and so on. CEAs and CBAs are most centrally concerned with economic efficiency.
>
> "The other listed factors represent primarily different concerns. Formal CEAs or CBAs have only been infrequently used in making policy decisions. However, pressures for more cost-effective decision-making could result in greatly increased use of such analyses. The Office of Technology Assessment is conducting a study of the effects, or implications, of using cost-effectiveness analysis and cost-benefit analysis in decision-making concerning medical technologies."

As you will note, "CEAs and CBAs are most centrally concerned with economic efficiency."

To carry out its charge, OTA has farmed out a number of studies. Early last month draft copies of some 18 documents were sent to the Association for review and comment. The areas under study include Neonatal Intensive Care, Cervical Cancer Screening, CT scanning, Breast Cancer Surgery, Orthopedic Joint Implants, the Artificial Heart, Cardiac Transplant, Elective Hysterectomies, Bone Marrow Transplant, Cardiac Radionuclide Imaging, Cimetidine and Peptic Ulcer Disease.

As the OTA boldly admits, its economic approach, the National Center for Health Care Technology (NCHCT) hopes to use a scientific approach, but economics has already raised its ugly head.

The NCHCT and its National Advisory Council were established by Public Law 95-623. Dr. Seymour Perry is the Center's director. He operates under the supervision of Dr. Ruth Hanft, who is an economist. They spent five hours at Chicago AMA headquarters on explaining their program to Dr. James Sammons, AMA's Executive Vice President and his top staff. The points they stressed were that the program is non-regulatory in nature and that they wanted input from the practicing community.

Briefly, the Center will operate as follows: on the advice of its Advisory Council, it will arrange for studies to be made on various subjects. These studies will be massaged by the Advisory Council and then published in the *Federal Register* for public comment. After study of the comments, the final documents will be published.

The National Advisory Council consists of 18 people from the fields of medicine, hospital administration, research, economics and the public. Dr. Charles Sanders of Massachusetts General is its chairman. Dr. Robert Ebert of the Millbank Foundation has been nominated for a second term. The AMA has nominated Dr. Lonnie Bristow of California, a practising internist and a member of its Council on Medical Services, to serve on the Council.

The Council has established two subcommittees—one on criteria and research and one on reimbursement. The subcommittee on reimbursement has only had one meeting—for the purpose of organizing. The subcommittee on criteria and research has been somewhat more active and has set as its goal a review of old technology, new technology and emerging technology. They are bandying about research papers on alpha-fetal protean, coronary by-pass surgery, heart transplants, caesarian sections, and the use of dental x-ray.

Doctors Perry and Hanft are determined to move cautiously. They turned down an offered $25 million to get the program off the ground, requesting only $7.8 million. They are going to have an opportunity to be even more cautious—the revised budget has cut them from $7.8 million to $4 million.

I would make two observations at this point. First, notwithstanding their desire to move cautiously, I fear that when OTA publishes its documents, NCHCT will have to move.

Second, although not required by law, NCHCT has been given the responsibility to advise HCFA on the payment of services under the Medicare program. I don't want to leave the impression that this will be a major activity, but with other pressures that exist, it could develop.

Now, the HCFA's Medicaid Management Information System. Basically, it is an attempt to avoid fraud and abuse and bring uniformity in reporting to the Medicaid program. The Law provides the states an incentive—90% of the cost—to set up the system. It also authorizes 75% federal payment for its operating costs. Its ultimate goal is to save money—and hopefully it will speed up payments to providers. Where it has been implemented, it has not been without problems.

Twenty-seven states, including New Hampshire and Vermont, have been certified as meeting the MMIS requirements. I am not sure that Vermont and New Hampshire meet all the requirements because 15 of the states were "grandfathered." Twenty additional states, including Maine and Massachusetts, are in advanced planning for certification. I understand that Massachusetts' activities have had a setback in that the state's contractor for the program filed bankruptcy. I am not sure of the status of Connecticut and Rhode Island.

All states not grandfathered will have to meet all MMIS requirements to be certified. All grandfathered states will have to meet all requirements by late 1982. The final regulations were to be issued by the end of last year but were not. On March 27, HCFA announced its intention to issue proposed regulations in the near future.

How will the MMIS program affect practicing physicians? *Right in his office!!* The program calls for the use of a uniform claim form and for the use of uniform coding systems for diagnoses and for procedures. Recognizing that the computer is not going to go away, the AMA has been working with HCFA to develop an acceptable claim form. This work has progressed to the point where it is hoped that the form will be in use by next Fall. The next step is to make the form scannable by a computer.

Scannable forms are in use in four states—Florida, Michigan, Minnesota and Wisconsin. California started its program in January—it was followed by a series of explosions. It seems that the program was first applied to pharmacists. The California Hospital Association watched with fascination as 12 pharmacies went out of business. They sued for a postponement and were successful. They are now seeking relief in the legislature.

The program was to apply to physicians beginning March 1. The California Medical Association has been successful in postponing the effective date until June 1.

From this distance, at least a portion of the problems in California seem to stem from personality clashes with the Director of the State Department of Health, Beverlee Myers.

It is my understanding that approximately 18 other states now require physicians' offices to use diagnostic and procedure coding. After an initial period for familiarization in at least two states complaints have quieted down. This resulted from the state societies being in on the early planning.

With respect to coding, you are all aware of CPT-4. Julie Richmond is the 8th Assistant Secretary who believes we need a uniform language for procedures. Len Schaeffer is the first bureaucrat to do something concrete about it. He has entered into an agreement with AMA to use CPT-4 as the basis for its procedural code. This move is supported by Blue Cross and Blue Shield and the commercial insurers. It is opposed by the American Hospital Association.

From the point of view of the practicing physician, after an initial trauma to train his billing clerk—after all the quirks are worked out—in theory, at least, the program should be to his benefit. He will be paid more quickly.

The number of diagnoses and the number of procedures performed by the average physician are limited. In some cases, they can be listed on a single page. The use of digits will be easier and more accurate than trying to type out Wegener's Granulomatosis or cholecystitis.

The purposes of the two programs I have discussed are to save money for the government. If they are carried out properly they can result in a benefit to the patient and physician as well. To assure that the latter occurs, it will be necessary for your state societies to be involved. Involvement begins with your individual states. You all know that!

Involvement also includes the federal regional offices. I know this can be a great source of frustration, but it is said that the regulators soon become the protectors of the industry they regulate.

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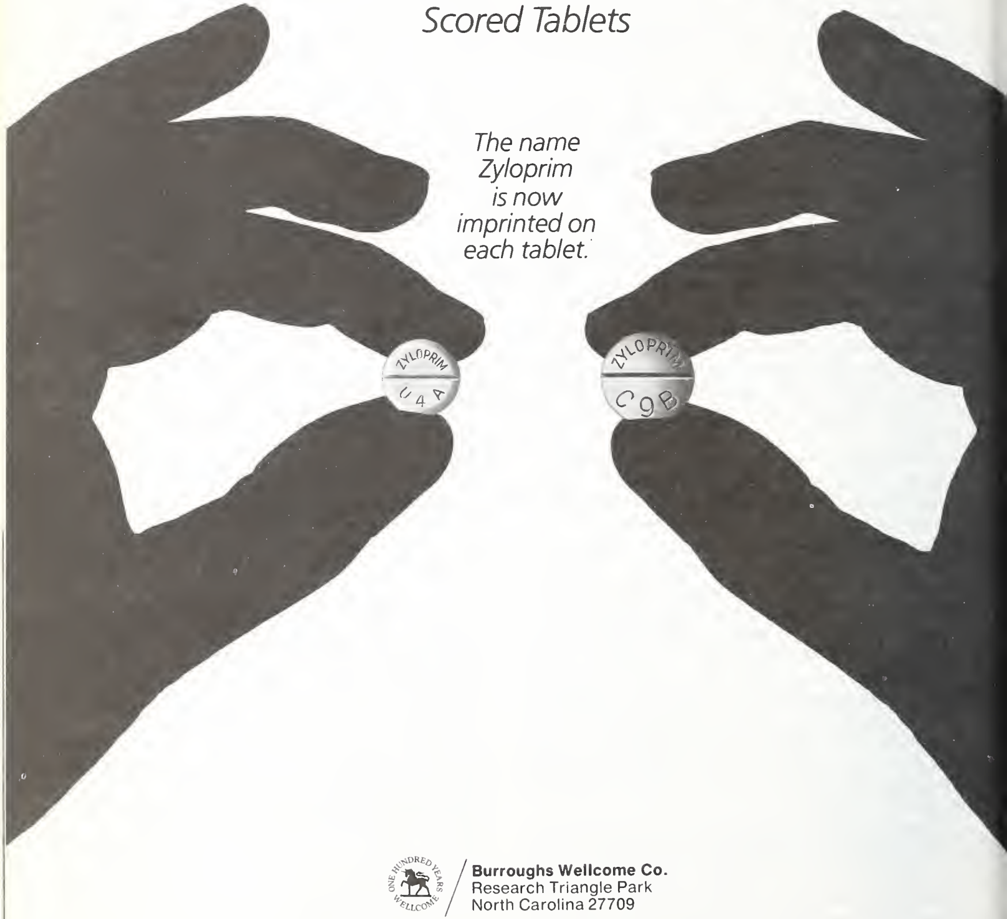

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Some Notes on Critical Care Units

BERNARD V. STRAUSS, M.D.

Coronary and Intensive Care Units in general hospitals are now widely considered to be a boon to optimum patient care. With increased experience there has been continued improvement in the planning of the architecture; in staff selection, training and expertise; and in sophistication of the monitoring and therapeutic equipment on the units. It is generally believed that a number of lives have been saved as a direct result of the availability of these special treatment centers.

Along with providing expert physical care, the personnel of critical care units are increasingly aware of the need to recognize and deal appropriately with the psychological stresses which affect them as well as their patients. The crisis atmosphere of the units is especially hard on the nurses. They work under constant tension and literally invest much of themselves in the care of their patients. Deaths are often taken, at least in part, as personal failures. The nurses do their work, and then may go home and cry. It is a very difficult and exacting job; fortunately, it is also frequently a most rewarding one. We shall discuss below some of the psychological aspects and some preventive and remedial measures that may help to lessen tension and contribute to patient care.

General Unit Atmosphere

The ideal general atmosphere in such units is one which is quiet, confident, optimistic, encouraging, and steady. Sudden, quick, and jerky movements are threatening and frightening to many patients and are to be avoided. There should not be too much chatter within the patient's hearing; and what talk there is should be of a helpful and encouraging sort. Conversations concerning personal affairs of the unit's staff personnel should be kept out of patients' earshot. It is important to remember that these very sick people are particularly likely to personalize, exaggerate, misunderstand, and misinterpret—all in keeping with their understandable apprehensions. This can create serious problems and can have untold detrimental effect.

Need to Individualize—the Patient's Personality

It is important to treat each patient's care and aftercare in terms of that individual's personality and life circumstances. There will be differing reactions to the anticipations and the problems of adjustment to new status, to restrictions on activity, to the need to continue to depend upon medication and the awareness of a possible continuing threat to health and to life. These may be variously experienced by some patients as overwhelming anxiety, depression, hopelessness, body image confusion or concern over loss of sexual powers. Others will deal with their apprehension or anger by displacement, projection or massive denial.

Some will have a need to know, to feel that they are in control. These are individuals who have always directed their own lives; they are accustomed to initiate action, not merely to react. They will want to know the details of what is wrong with them, what the treatment plan is to be and its rationale, what is their prognosis, and just what they can do to help themselves. Others will be quite ready to be taken care of, to be told what to do each step of the way. These individuals would feel burdened and likely to be overwhelmed unless given appropriate emotional support. Each should be treated in a manner appropriate to his particular personality needs. It is an important part of the physician's responsibility to make this assessment. The physician needs to be wary of the current fashion of indiscriminate full disclosure, without due regard for special circumstances. In some instances this is quite unnecessary and actually gratuitously anti-therapeutic. One must reserve the right to discriminate and to exercise one's own judgment—always with the patient's ultimate welfare as the central goal.

The Role of Relatives

With relatives too, it is very important to individualize. In some cases, visits from relatives can be very helpful; in others extremely disruptive. For many patients there is much relief if a familiar face is seen in the frightening, strange surroundings of the unit. Conversely, a visit from a hostile spouse or someone whose motives a patient may consider suspect can cause considerable anxiety and turmoil. The doctor or nurse, frequently the latter, is in the best position to sense the patient's response to the particular visitor and can then adjust the individual's visiting schedule accordingly.

Need for Detached Concern

It is essential that physicians, the unit's nurses, and other personnel avoid making personal issues of the patient's behavior. Reactions of the frightened, anxious and apprehensive patient may include belligerence, demanding behavior, abusiveness, disruptive acts, and criticism of personnel. If such behavior is properly interpreted and understood, it will be possible for the care-giving person to continue to be kind and empathic, while at the same time maintaining the necessary firm,

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BERNARD V. STRAUSS, M.D., Chairman, Department of Psychiatry, Danbury Hospital, Lecturer in Psychiatry, Yale University School of Medicine; Clinical Professor of Psychiatry, New York Medical College, New York, NY.

supportive attitude. Sensitivity to the patient's plight and subjective thoughts and feelings concerning family, future, ego ideal, and body image should be cultivated. With many patients it will be helpful to explain, to the extent of their capacity to understand, the protective "guardian angel" purpose of the various machines, devices, and procedures—all of which are probably new, mysterious, and frightening to the patient. The anxiety of other patients can be much relieved by clarification of misconceptions regarding their illnesses. Drawings can be helpful. If his physical condition permits and the patient wants to talk about his feelings and apprehensions, give him the opportunity to ventilate. If he should become acutely paranoid, don't get into a hassle with him—remain calm and steady—be aware of his projections as a defense against his fears. In such cases it is generally advisable to seek psychiatric consultation.

Interaction of Patient, Family and Care-Givers

The various individuals who will be involved in one way or another when a patient is in a special care unit may have different and, in extreme instances, even incompatible interests; i.e., the patient, family, nurses, attendants and doctors. A cooperative and competent team can certainly provide the best care for the patient.

The **patient's** major concern generally involves getting the best possible medical and nursing care and repeated reassurance; but some patients "give up" and may exhibit a "let me die" attitude. This may be expressed when the patient feels unable to tolerate his incapacity or the insult to his body image. He can't stand the thought of being crippled or disfigured or no longer the family breadwinner.

For its part, **the family** will express varied attitudes depending on their prior relationship with the patient, which may have been one of love and devotion or could have been hatred and hostility. In the critical care units the latter often engenders guilt feelings. Each of these attitudes will have an effect on the patient; some of these effects will be salutary, others will be disruptive. The family may actually blame the patient for his plight; they may blame themselves, the patient's spouse, his employer or anyone else. The timing of the expression of these attitudes to the patient may have a seriously adverse effect upon the patient's state of mind and his physical status as well.

The performance of **nurses** in the difficult atmosphere of the critical care units will, of course, vary with their personalities. The reasons which led to their becoming nurses will have an effect upon how they perform their duties. Some will be dedicated, some mothering, some matter-of-fact; and for some few, it will be just a job. There will also be some nurses who will derive particular satisfaction from the exercise of power. The patients are weak and dependent. The nurse may react to this in a manner which will be either beneficial or detrimental for the patient's welfare, depending upon how it is used. If supportively, it will be helpful; if domineeringly, it may promote poor patient compliance and lack of cooperation. Some nurses will unquestioningly accept the physician's authority; others will resent it and this resentment may be unwittingly expressed in subversion of that authority, particularly when the doctor's attitude is itself inappropriately overbearing.

Aides and attendants are generally the lower-paid and lesser-educated members of the caretaking team. While many are dedicated and do a wonderful job, some resent their position and do not treat the patients with appropriate consideration. Some of this negative behavior is expressed in covert hostile ways. The likelihood of such undesirable behavior is substantially minimized in those units where the physicians and nurses are aware of the position of the attendants, give recognition to their contribution, and treat them with consideration and respect. In common with most of us, the attendants in such units are likely to respond favorably and to take pride in their work.

As far as the **physicians** are concerned, it is urgently important that they not fall under the spell of the machines and forget the patient as a person. With all the modern technology available and present in modern day critical care units, the doctor may become preoccupied with the blinking lights and fail to be aware of the patient who may have "given up." The doctor's general attitude should be one of encouragement. He should give the patient an opportunity to talk with him. He should call for psychiatric consultation when indicated as an elective act rather than a summons to meet an emergency.

The matter of **religious rights** in the case of very sick patients is one that calls for the exercise of fine judgment. For some patients calling in the priest, minister or rabbi may be very comforting. Other patients will be needlessly panicked. It is not enough to note the chart record of religious affiliation. Within the different religions there are many degrees of devotion and belief. To the extent practicable, it can be very helpful to know the particular patient's attitude toward his religion before prescribing for him.

There are some patients for whom the relative impersonality, lack of privacy, and general crisis atmosphere of a critical care unit may have an adverse effect. Here, again, as in so many other situations, where possible each patient should be treated according to his individual needs, not according to a formula. Critical care unit nurses need to be constantly alert to signs of increasing anxiety, depression, disorientation, delirium, and hints or expressions of suicidal preoccupation. Each requires a different and an expert management. For some few patients whose physical condition otherwise permits it, earlier than usual transfer from the unit may be indicated—and for such patients may even be life-saving.

Hypnotic Drugs and Treatment of Insomnia

AMA COUNCIL ON SCIENTIFIC AFFAIRS

In 1977 an expert panel of the National Institute on Drug Abuse (NIDA) addressed the question of whether short-acting barbiturates were too often being abused or misused, were contributing to a high rate of suicides, were too readily available on prescription and should perhaps be moved from Class II of the Controlled Substances Act (CSA) to Class I (CSA).[1] This committee concluded that there was no good evidence to suggest that any new regulatory action should be taken against these barbiturates. It did suggest that benzodiazepines were perhaps preferable to barbiturates as hypnotics, because of a wider margin of safety, but concluded that hypnotics had an important place in clinical practice that did not deserve to be truncated because of their possible abuse potential.

In 1979 another expert committee of the National Academy of Sciences' Institute of Medicine (IOM) again reviewed these issues and others in a more detailed report on "Sleeping Pills, Insomnia, and Medical Practice."[2,3] This committee examined prescribing habits of physicians in the treatment of insomnia and reached several important conclusions, including the fact that both short-acting barbiturates and benzodiazepines as classes of drugs are probably equally effective in short-term use. In long-term use, whereas the barbiturates more rapidly lead to tolerance, the benzodiazepines carry increased likelihood of the adverse effects of impaired coordination and psychomotor skills. Either type of hypnotic may be preferred for a particular patient depending upon his individual characteristics. This committee also recommended no change in classification of these drugs, but it did make several findings and recommendations important to practicing physicians.

The Council on Scientific Affairs has reviewed these two reports and agrees with most of their substantive conclusions. The following is a distillation for the clinician of these two excellent reports together with commentary.

Use of Sedative-Hypnotics

Physicians' prescribing habits have changed since 1970. As of 1977 prescribing of all hypnotic drugs has fallen by 39%. Barbiturate prescriptions have declined by 77%, because of their restriction to Class II (CSA), while flurazepam hydrochloride (Dalmane), and the other benzodiazepines (e.g., Valium, Librium) have increased to account for more than half of all sedative-hypnotic prescriptions.[4] The shift to flurazepam (Dalmane) can be largely attributed to its diminished interference with REM sleep, the clinical importance of which has never been scientifically established. Its claim for a greater efficacy over a four-week period may also have influenced some prescribers, although this was based on a single study involving ten carefully selected subjects. Clearly, more controlled studies in this area are indicated.

Barbiturate-related deaths in the United States have decreased between 1970 and 1976 by more than 50%, in parallel with the reduction in total number of barbiturate prescriptions. Nevertheless, total suicides reported from all causes increased slightly during the same period and that number related to drugs changed less than 10%. This suggests that people bent on suicide may easily find alternative means to achieve death, such as alcohol-drug or multiple drug combinations.

Management of Insomnia

Insomnia is a symptom, rather than a disease entity. The differential diagnosis of insomnia is now reaching new refinement from well conducted studies in a few interdisciplinary sleep research laboratories. The importance of recognizing the underlying disorder cannot be stressed too often. In such organic disease states as congestive heart failure or symptomatic hypertension, the temporary treatment of insomnia by hypnotics can be important in re-establishing compensation just as correction of the disorder may relieve the insomnia.

EDITOR'S NOTE: This is a report of the AMA Council on Scientific Affairs to the House of Delegates at its Annual Meeting in July, 1980.

Psychiatric conditions such as depression, mania, organic brain syndrome, alcoholism, schizophrenia, and so forth may also present with the symptom of insomnia. To treat these latter patients with a hypnotic has dubious value and, if enough doses are prescribed, may contribute to a suicide. The administration of a hypnotic drug to the patient with sleep apnea may prove fatal and is contraindicated. Thus, a careful history and an accurate diagnosis should be sought before using sedative-hypnotics for insomnia.

Temporary and situational insomnia related to environmental distortions may respond well to judicious use of hypnotic drugs with close physician monitoring, no less than that related to acute exacerbations of organic disease. Both panels of experts suggested that chronic use of hypnotics nightly for more than two to six weeks was not justifiable. Not enough emphasis has been placed upon other measures for treatment of insomnia than drug therapy.

Recent studies of insomnia have shown great overlap in actual sleep patterns observed in the 15% who complain of this symptom and those 85% who do not. The symptom is widely prevalent: over 30% of adults surveyed in Los Angeles complained of some difficulty sleeping, although only about half considered the problem serious.[5] Of the 6% who consulted a physician about half received a prescription for a hypnotic. Thus, insomnia is not routinely treated with a drug and, in fact, may not require drug treatment much of the time.

Non-drug treatment of insomnia should receive particular attention by physicians in those patients with chronic, persistent primary insomnia. Psychotherapy and behavioral therapy have their place in difficult cases, but compliance may be limited. Office counseling can be helpful and should, according to the IOM report, include advice to: establish rigid times for retiring and arising from bed; avoid naps; avoid stimulants, including coffee and tea, in the afternoon or evening; use the bed only for sleep or sexual activity; pursue some program out of bed at times of wakefulness; establish a regular program of daytime exercise; plan evening activities conducive to relaxation: hobbies, rest, hot milk, etc. Much more comprehensive study is needed to define the relative importance of these empirical suggestions for selected groups of patients.

Hypnotic drug therapy should be used judiciously and for brief periods of two to six weeks. The choice of drug and the frequency and duration of its use should be tailored to the individual needs of the patient. The effectiveness of short-acting *barbiturates* is well established. However, there is a hang-over effect the next day, tolerance may develop quickly with regular daily use, the suicidal dose is relatively small, and insomnia or nightmares may complicate withdrawal.

Benzodiazepines are probably as effective at inducing sleep as the barbiturates, although experimental documentation of this clinical impression is not conclusive. Their therapeutic index is higher than that of the barbiturates. The benzodiazepines break down into clinically important psychoactive metabolites with half-lives of one to eight days that cumulatively can produce adverse effects upon daytime coordination after nightly use of the drug for a week or longer. In addition, adverse effects are more likely to occur in older patients and in patients with impaired kidney function.

The elderly patient is not only more subject to sleep difficulties, but is also more vulnerable to the hazards of hypnotic use. This is because of the greater likelihood that these symptoms are due to disorders that do not respond to, and may even be aggravated by, hypnotics, such as:

- Depression
- Senile Dementia
- Organic Brain Syndrome
- Alcoholism
- Renal Disease

Thus, the benefit/risk determination in older people may be difficult to make. Failure to control insomnia with one hypnotic may easily lead to use of combinations or to overuse.

Conclusions

Hypnotic drugs, in spite of the above caveats, still play an important adjunctive role in the management of organic disease, as well as in the management of some insomnia. Their intelligent use in the lowest effective dose is an important part of every physician's armamentarium.

Any effort to curtail, in the name of drug abuse, the range of pharmacologic choices that the physician has should be resisted. The Council agrees with both of these prestigious panels that there is "no justification for more restrictive scheduling of barbiturate hypnotics under the Controlled Substances Act." Although no one in the United States has seriously suggested that barbiturates or benzodiazepines be removed from medical practice, indications can be removed from labeling, and from there it is one step to enforcement of adherence to that labeling in state law and regulation, on penalty of license removal or restriction. That could happen with any drugs that have a dependence liability and abuse potential.

Drug abuse will be with us until we successfully address the complex reasons for its prevalence. It will shift from one substance and class of substances to another, if prescribing and production are curtailed for first this drug and then that drug. To assess drug efficacy and safety for the individual patient only in the context of drug abuse and physician misuse is hazardous. Such myopia deceives the public and denies the benefits of drug therapy for some patients thus ultimately endangering their health.

The Council on Scientific Affairs believes that the sedative-hypnotics have an important place in contemporary medical practice. The use of these drugs may be aided by more clinical investigation, epidemiologic studies, and sophisticated multidisciplinary (pharmacologic, psychotherapeutic, behavioral, and psychosocial approaches) research. This research deserves both federal and private financial support in addition to the support of the pharmaceutical industry, which is presently the principal source of funds.

The Council recommends that the AMA continue to place emphasis upon the diagnosis and management of insomnia, as well as upon the use of sedative-hypnotic drugs, in undergraduate, graduate and continuing medical education.

The Council also recommends that the AMA support the IOM Committee's suggestion that the current scientific issues associated with sleep disorders, their study and treatment require serious review; that this goal be accomplished within the present administrative structure of the DHEW, rather than by the formation of still another major institute; and that the AMA volunteer to cooperate in this review.

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Communication: Talking and Listening

ADDRESS OF ROBERT B. HUNTER, M.D.

PRESIDENT OF THE AMA

In ascending to this splendid office, I bring you a plain message. It centers around communication.

By that I mean the kind of communication that involves listening as well as talking. I mean the face-to-face, sit-down-at-the-same-table, honest give-and-take kind of communication between all segments of our society on the urgent health care problems of the day. And I mean active, as compared to passive, communication. I mean mutual communication that leads to a mutual understanding of the problems, and to mutual commitments in their resolution. I'm convinced that this kind of communication is absolutely vital to the future of our profession and of our association, and thereby to the future health of the people of this nation. Therefore, I'm also committed to so communicate, on this occasion, and during the coming year.

From within this framework, then, let's examine some of the urgent health care problems of the day. As this audience is well aware, the most visible, the most persistent, and the most difficult-to-deal-with problem is the steady surge in the cost of care. I believe a large part of the difficulty has been created by our society's failure to recognize a single, basic fact.

Since every element of our society has contributed to the cost problem, every element of our society must contribute to its resolution. Unless and until that happens, the various solutions that we undertake are going to be piecemeal, rather than of a piece. Well, I also happen to believe that it's squarely up to the American Medical Association to exert the leadership necessary to bring together various elements of the health care system—as well as other elements of our society, including government—to fashion comprehensive and cooperative remedies for health care problems, with emphasis on the cost problem.

To show you what I mean, and from the perspective of the problems on the health care table, let's do some talking and some listening to the other elements in our society. When we physicians talk about government's place at this table, we've never been shy about expressing any misgivings that we may have. Very often these misgivings are justified.

If I were presently talking with members of the Carter Administration, or the Congress, for example, I might remind them of their repeated assurances that in government initiatives to reduce the costs of patient care, there would be no reduction in the quality or sufficiency of that care. And I would ask, why is it, then, that in current federal budget deliberations, there is so much talk about reductions in the funding of federal commitments to improve health services for some segments of the population? If government is sincerely interested in assuring the American people of the future quality of medical education and practice in this country, why is its support of basic and clinical research badly wavering or at least uncertain, and why is its support for medical education apparently about to become minimal or eventually nonexistent, especially since these are the very wellsprings of tomorrow's medical breakthroughs?

There are related questions that could be asked of other elements of our society, including representatives of the insurance industry, and of business and industry in general.

In responding to the waves of enthusiasm now washing around the concept of more competition in the health care market, are provisions being made for rough as well as smooth sailing?

To what degree should a complex, personalized service like health care even be marketed? Are patients really consumers of a product called "health care," with the implicit assumption that this consumption can be increased or decreased at will with little or no consequences for patients? Can physicians or hospitals

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ROBERT B. HUNTER, M.D. of Sedro Woolley, Washington, AMA's 135th president, delivered this address at the Annual Meeting of the AMA House of Delegates, July 23, 1980, Chicago, Illinois.

call some central health care warehouse and order up a batch of patients with the same sex, size, shape and sensitivity, and with identical or even similar medical problems, and thus make more efficient and productive use of expensive facilities and equipment? Exactly how close a correlation should there be between the utilization and the purchase of medical equipment? Will those planners and economists who opt for an exact correlation feel the same way when they are the ones admitted to a hospital emergency room with a life-threatening medical problem, only to find a vital piece of equipment missing? To forego such a purchase in business or industry may be sound economics, or may merely mean the loss of an unprofitable order. In medicine, it may mean unprofessional diagnosis or therapy, and perhaps the loss of life.

There is a single, very basic question that might be asked of the public-at-large. Is there really even a small group of people in this country over the age of 15 who actually don't understand at least the rudiments of personal health promotion, who actually don't know what excessive amounts of tobacco, alcohol, and calories, with little or no exercise, can do to their lives and their longevity? And aside from periodic warnings to patients, what is the physician's role in this? Should we plead, cajole, coerce or threaten? Should we become paternalistic, or maternalistic? Should we really take on the role of general health counselors, and attempt to advise patients on jobs, sex, marriage, mental health, and the eternal vicissitudes of life in general?

Such are some of the questions that we might, and we have, asked ourselves and the other elements in our society. But if you'll recall, my definition of effective communication involves listening as well as talking. And the people we've been talking to have posed some equally sharp questions for us to answer. The public-at-large has such questions.

American physicians today are superbly educated and trained. And we do have sophisticated, up-to-date equipment and facilities to aid us in the provision of high-quality care. And patients, as well as our larger society, are grateful for the excellence of that care. But to actually deliver this care to the patient necessarily requires concentrating all the technology and personnel in one location. In the delivery of acute care, this location is almost always a sophisticated medical clinic or community hospital. We physicians see these resources and the obviously complex delivery system as absolute imperatives to the practice of modern medicine. But patients may have a less charitable view, particularly in humanistic terms.

The patient may be successively shifted from generalist to specialist, from office to hospital, from X-ray to laboratory, from attending physician to duty nurse, from physical therapist to social worker. And since this often is the case, patients may ask: "Have those of you who complain about bureaucracy in government ever taken a good, long look at your own?

Humanism in medicine, after all, is just another way of saying "I care." And patients are telling us that while the delivery system, and the people in it, care *for* them *very* well. Does the System, and the people in it, care *about* them as well?

People in government are telling us that the tens-of-billions of dollars it annually contributes to health care now add up to about 42 per cent of the total health care dollar, and the subsidization of about 38 per cent of all personal health services provided. Since that is the case, they ask, aren't those people—including physicians—who maintain that government should have little or no input into health care policies living in a dream world? Meanwhile, the Congress has many health care constituencies, of which our profession is but one. And the people in Congress are telling us they aren't receiving a whole lot of letters complimentary to the health care system these days. What they're receiving are letters of complaint.

Since that is the case, they ask, aren't there in fact some real problems—especially cost problems—out there in the health care world? And what is medicine, and organized medicine doing about them?

In like manner, the people in health insurance, and in business and industry, are telling us that today the premium dollar is at a premium. Yes, they say, we do have the finest system of medical education and practice in the world in terms of quality. And yes, our community hospitals are among the most modern and best-equipped facilities of their kind in the world. And yes, all but about 10 per cent of Americans have financial access to the system through private and public insurance programs. But costs of all this are going up and up. And since that is the case, they ask, what in the world can be done to rationally restrain costs? Should the open-ended insurance system of paying for most of the costs of health care be closed to an extent? Should there be more competition in the systems for financing and delivering care? Should both physicians and patients assume more responsibility for their contributions to the cost problem? Are most of us physicians really aware of the costs of common tests and procedures? Do most of us physicians occasionally review a patient's hospital bill?

These are some of the hard, health care questions now being asked in our society. And in seeking to find answers to the questions, leaders from all elements of society have been doing a lot of talking, and listening, of late. Because effective leadership presupposes effective communication, or the ability to pay at least as much attention to someone else's point of view as you do to your own. Parenthetically, the ability to listen to other points of view, and to respond accordingly, is evident in many of the activities of the AMA, and the activities of its Auxiliary as well.

The AMA is on record in favor of filling any gaps that exist in health insurance coverage in this country, including government assistance when appropriate. Our policies against alcoholism, smoking, obesity and a host of other public health problems, are a matter of recent record. While our Auxiliary has literally brought home to millions of Americans the life-giving value of personal health promotion. During the past two years, public service announcements with specific information on how people can "shape up for life" have been beamed to thousands of radios and TV sets in thousands of American homes. Furthermore, the Auxiliary has established direct programs in more than 500 communities in the nation, programs that directly involve thousands of people in proper nutrition and physical fitness.

While the AMA's headquarters staff is reorganizing certain programs around actioneering, as contrasted to pamphleteering, in health education. Through on-site visits and in other ways, we will be helping local medical societies, and local physicians, to reinforce the message of personal health promotion. I might add and urge the thousands of practicing physicains in this country to involve themselves in carrying this message to patients. Because it is in the three million physician-patient contacts that occur in this country every day that personal health promotion can be most effective. People immediately concerned about their health are more likely to act accordingly, and act now.

AMA leadership also is evident in our policies and action programs with respect to the health care cost problem. Our corporate visitation program has resulted in the creation of planning and action programs at both the national and local levels to bring business and health professionals together in common cost containment cause. As you know, the AMA is a key sponsor of the Voluntary Effort to Contain Health Care Costs, or VE, and the AMA was the sponsor of the deliberations and subsequent recommendations of the National Commission on the Cost of Medical Care. But in each instance, the point of view of other concerned elements of our society, public as well as private, have been represented. And there are both palpable and potential benefits.

The VE has provided up to three-point-five-billion-dollars' worth of benefits to the American people in terms of money that would otherwise have been spent for hospital care. Parenthetically, what we've done and are doing through the VE and the national commission we've done and are doing voluntarily. And the process hasn't called for the creation of new regulations. It hasn't established a new bureaucracy.

It has provided a first-of-its-kind-in-history national forum for face-to-face, sit-down-at-the-same-table, honest give-and-take, communication between all segments of our society on urgent health care problems. And the process has provided a voluntary, private-sector consensus, and coalition, with government representation included, as rational alternatives to intervention by government. Which explains why the U.S. House of Representatives, in its wisdom, soundly defeated the Carter Administration's hospital cost cap bill last fall. And which also explains why the AMA House of Delegates, in its wisdom has approved our participation in the Voluntary Effort, and has adopted most of the cost commission's recommendations in whole or in part.

Obviously, in so acting, neither House got everything that its members might have asked for, or wanted. But they talked, and they listened. They were willing to place the public interest ahead of personal interest if the occasion demanded it. They communicated. They demonstrated leadership.

All of which brings us, in turn, to what I believe is the most crucial challenge by far to American medicine and to the AMA at this most crucial point in time. The challenge is in fulfilling the potential benefits of voluntary cost containment activities.

How do we convince the other elements in our society that the consensus and the coalition exemplified by the VE and the national commission are not just passing things? How do we convince them we will continue to support the national forum provided, and that we will remain committed to the overall goals of this forum? In short, how do we extend our leadership in helping our society deal with health care problems at hand and on hand?

I believe we must continue to exercise the best kind of communication, which is by example. We must continue to act as well as react. We can take the AMA's national corporate visitation program, and turn it into many local action programs that will be responsive to local health care needs.

We can remind ourselves that when the Voluntary Effort ultimately has served its purpose, it can live on in spirit and in substance through the long-range recommendations of the national cost commission. This will happen, that is, if action programs to implement the commission's recommendations are given the highest priority by all institutions involved, and particularly by the health care system itself, by the medical profession, and by the federation of organized medicine.

Moreover, we must be willing to so act even when we're the ones with bullets to bite. For example, those of us in medicine, and the federation, have been quick to tell government where budget cuts should not be made, as in medical education and medical research. But we've said very little about where such cuts could be made, including areas where our own interests may be at stake. What that boils down to is "suitable" leadership, or leadership exercised primarily when it does suit us.

What we must demonstrate to government and the people within the next few years is "selfless" leadership. We must demonstrate, conclusively, that we've got the medical ground and the courage to make the pivotal decisions necessary for the allocation of scarce health care dollars, even if some self-sacrifice is required.

To that extent, then, this kind of leadership is not without its own costs. But leadership that costs nothing usually is worth nothing. No one knows that any better than the leaders of this federation. Because such leadership by the federation has meant a great deal of late to our society, and to our profession. Isn't that why this association, its delegates, its trustees, and its staff, along with like segments of state and local medical societies and thousands of physicians across the country, in concert with representatives of the AHA, the FAH, and the other private and public institutions involved, sent out the ringing message of the Voluntary Effort, and endorsed most of the recommendations of the cost commission, even those contrary to established policy? Doesn't this also reflect a recognition by our leadership that while the demands for health care are infinite, private and public funds to meet these demands are finite, and getting more so in today's uncertain economy?

And finally, as our society makes the crucial decisions necessary to strike a reasonable balance between demands and dollars, doesn't all of this mean that those of us in American medicine must demonstrate to our society, right now, today, that we are willing and able to share our health care knowledge and expertise, and that we are willing and able to help society strike a health care balance that is reasonable—especially in terms of the real needs of our patients?

And isn't the American Medical Association the only organization that can represent all elements of medicine, and hence can so represent medicine, to and with the other elements of our society?

None of this is to take credit for, or detract from, the leadership displayed by other medical organizations. To cite just one of many examples, our medical schools, with strong support from medical students and housestaff physicians, are reemphasizing the need to care about patients as well as for them, and to instill cost consciousness as well as clinical consciousness in medical education and training.

But here, too, the AMA has been talking, and listening. With the addition of the medical school, medical student, and housestaff sections to our House of Delegates, we have been talking and listening to medical educators, students, and resident physicians.

We have been telling them to come into all of the medical family members represented in the AMA, to help resolve the health care problems of the day. And they are joining us. More than 40,000 students and resident physicians have come into the fold.

Meanwhile, medical educators, along with women physicians and foreign-trained physicians, have been given priority status in current AMA membership efforts. Last fall we mailed the brochure entitled "AMA's New Voice in the House: The Academician," to medical educators throughout the country. And the letters they sent back speak well for medical schools, and for the AMA.

One academician said: "I would be very much interested in learning more about the (medical school) section, and (in) discovering ways in which I could contribute to its success." Another commented: "We appreciate very much the interest of the American Medical Association in education, and in turn support your goals." And an educator who recently joined the AMA said: "Only now do I realize the tremendous importance of AMA participation in medical education, (in) planning the health care of patients, and (in) guiding the sponsorship of health programs by the federal government."

We at the AMA are hoping for the same kind of contributions, interest, and participation in seeking to add more women physicians, and foreign-trained physicians, to our ranks.

As a male, I don't pretend to fully understand all of the dimensions of the movement toward women's liberation. But as a physician, I very much appreciate the vital contributions, past and present, that women have made to medical education and practice. And as an officer of this association, I sincerely hope that many more women will join us, to help resolve the health care problems before society, and to make new contributions to medicine.

To physicians trained in other nations, I say: "When you came to America, you also became eligible to join the family of American medicine." And I sincerely hope that you, too, will join us, to talk and to listen, and to provide this association and this society with your contributions.

Parenthetically, there are certain unique contributions that both groups have to provide. The most important of these is a clear understanding, and a genuine appreciation, of the rights and the freedoms that those of us who live in this democracy are or should be privileged to enjoy. America and American medicine have enough detractors. We sorely need more supporters.

We who represent the AMA know that it has its share of detractors, including physicians—both town and gown—who elect not to join for one reason or another. At various medical meetings, I have listened to these physicians, and I've heard their complaints. Not all of the complaints are justified. I've met some physicians, fortunately few in number, who I have come to think of as the "medical moaners." They moan that their county or state medical societies or the AMA don't do this or don't do that, so they don't join. They moan that government, health insurors, business or industry, or what have you, should be doing this and shouldn't be doing that. So they establish or join splinter groups, and stand fast, and apart, on their own opinions.

To these physicians I say, "by standing fast you're standing still." It's high time to quit moaning, and get moving, in helping our society resolve the health care problems before it. To these physicians I say, "the only way we can fulfill all of our obligations to society is through the federation of organized medicine, including the AMA.

"So come join us." The AMA is harbor to all points of view, from liberal to conservative and all the shades between.

Some of the complaints about the AMA are justified. But then the AMA, like our society, has evolved along democratic lines. And the wheels of democracy can turn slowly, and not always in the direction that each of us might like. In listening to other elements of our society, we don't always hear what we want to hear, and our opinions, policies and programs don't always prevail. However, free and open debate, and the willingness to abide by majority decision, are the essence of democracy, and the essence of the AMA. And if AMA leadership positions occasionally hurt, they do so precisely because of people who *do* hurt, the patients we are bound to serve. Every physician as well patients we are bound to serve. Every physician in this country has a responsibility to be a productive citizen as well as a professional clinician. That's what AMA leadership, and our many beneficial activities on behalf of the profession and the public are all about.

Some years ago Dave Powers, then an AMA executive, said that, "Although many great and wonderful things are always going on at 535 North Dearborn, knowledge of these things too seldom gets out the front door." During the next 12 months I'm going to do my best to wear out that front door. I'm going to take the message of the AMA to the other elements of society, and to our profession. And I'm going to bring *their* messages back home to us.

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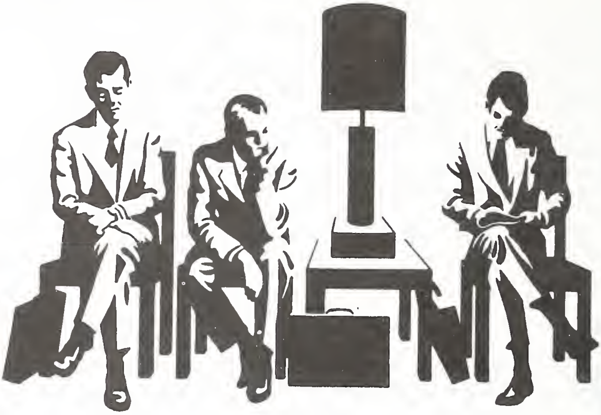

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Why Physicians Should Worry About Cost

JAMES S. TODD, M.D.

There is little disagreement that inflation is currently the number one issue. There are those politicians who would label health care as the number one culprit in this inflationary period. President Carter told the Congress that if they really wanted to so something about inflation, they would get a handle on health care costs. There is no doubt that medical care has become expensive. Some would say disproportionately so, while others would justify every cent that is spent. The truth is probably somewhere inbetween. Given the current climate and plethora of statistics I suppose selectively you can "prove" just about any point of view that you want.

It makes no sense to play the numbers game, for different figures mean different things to different people. Rather it is more appropriate to start with premises that all can accept. These are: 1) The amount of money spent on health care is steadily rising, 2) There may be ways of reducing that expenditure without reducing quality, 3) This is a legitimate concern of the profession, and 4) In today's climate, the alternatives to professional intervention are ominous.

Let's look at each of these premises in some detail. Why are expenditures rising? Writing in the November 1979 *Modern Medicine,* Theodore Cooper, former under secretary of HEW, listed six reasons: 1) Third party reimbursement policies increasing expectations and decreasing cost awareness, 2) The enactment of Medicare and Medicaid which turned patients and physicians more toward institutional care, 3) Labor-management agreements arousing interest and care and benefits as well as costs, 4) The trend toward specialization resulting from research and increased knowledge, 5) Increased cost of labor and personnel in hospitals, and 6) Expenditures in compliance with regulation estimated in some instances to be as much as twenty-five percent. To this I would add an additional three: the changing age of the population and the disproportionate use of resources by the elderly, the technological sophistication of the time with marvelous devices which are expensive to acquire and expensive to utilize but which result in more effective patient care, and lastly the physician's mentality. From the time physicians enter medical school, they are taught to do all things possible for all those with whom they come in contact, and in so doing have developed the finest health care system in the world, but in so doing have ignored cost and priorities. Health care can expand infinitely, and can legitimately absorb every dollar that society is willing to make available to it. We now know how to practice a style of medicine which if extended indiscriminately would be far more expensive than this country could or should pay, and certainly far more expensive than the meager improvement in health would justify.

Ivan Illich in his latest social blast, called *Medical Nemesis,* reaches the startling conclusion that the medical establishment has become a major threat to health. He sees that society has transferred to physicians the exclusive right to determine what constitutes sickness, who is or might become sick, and what shall be done to such people. This, he maintains, has resulted in the rituals, for example, of the yearly but probably unnecessary physical examination, the long term maintenance of the hopelessly ill, and the medicating of any and all conditions with the production of medicine as a commodity which if only extended far enough should assure good health. It is this medicalization of society which ends up spending thirty percent of the budget on ten percent of the people, increases the use of tranquilizers ten times that of alcohol, and in the end deprives the citizen of his ability to understand or determine his

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JAMES S. TODD, M.D., is engaged in the private practice of general and vascular surgery in Ridgewood, New Jersey. For five years he was Chairman of the Board of the Medical Society of New Jersey, and in July 1980 was elected to the Board of Trustees of the American Medical Association. Additionally, he has been on the A.M.A. Speaker's Bureau since 1972, Chairman of the New Jersey Delegation, and most recently Chairman of the Ad Hoc Committee to Review the Principles of Medical Ethics culminating in the adoption of the new seven Principles of Medical Ethics. Dr. Todd is also Chairman of the Board of the New Jersey Underwriters Inc. the physician owned professional liability insurance company.

This paper was presented at the 188th Annual Meeting of the Connecticut State Medical Society on May 1, 1980.

own medical future, not infrequently forcing the courts to make medical decisions. Illich concludes by saying, "The level of public health corresponds to the degree to which the means and responsibility for coping with illness are distributed among the total population. This ability to cope can be enhanced, but never replaced by medical intervention. The society which can reduce professional intervention to the minimum will provide the best conditions for health." Think about that for a moment, for as we are so busy studying more and more about less and less, it will not be much longer until no one in this country can be labeled as totally healthy.

Three things should be self-evident: 1) We cannot do all things scientifically possible for everybody everywhere all the time, 2) We must or somebody must decide what we are going to do for whom and where, and 3) Health care is only one of the determinates of good health (parenthetically we should be thankful that the American people spend almost as much on medical care as they do on tobacco, alcohol and cosmetics). Acknowledging these facts, who is in the best position to do something about it, certainly not the government—all they know is regulation and economic restraints with the bottom line becoming rationing. Certainly not the consumer, who clamors for more and more care at less and less cost. Logically then it becomes the health care system who should be able to most effectively address the issue of cost. Put most basically, it is in our best interest and in the best interests of our patients to do so. Being committed to good patient care and faced with finite resources, some alterations are imperative if the maximum number are to benefit from recent achievements. Hopefully this will be done in the same analytical dispassionate fashion with which the profession has attacked other medical problems it has faced in the past.

Let's look at the record so far. In 1976 the American Medical Association convened the Commission on the Cost of Health Care composed of physicians, laymen, and governmental people, economists, and hospital personnel. After a two-year study, this commission issued forty-eight recommendations all directed at improving the efficiency, effectiveness and economy of the health care system. In addition, as a result of the criticism of rising costs, the American Medical Association, the American Hospital Association, and the Federation of American Hospitals established the so-called Voluntary Effort whose role it was to decrease the escalation of hospital cost by two percent a year. This they have done and show every indication of being able to continue to diminish this escalation of hospital costs. When Tom Nesbit was inaugurated President of the American Medical Association he called for restraint in physicians' fees. Physicians have responded to this request as shown in 1979 when the consumer price index rose 13.3% and physicians' fees were only 9.4%. It would be inappropriate to emphasize physicians' fees as a major cost in the health care economy, for they represent only twenty percent of the health care dollar and if every physician's income in this country were diminished by one-half, the effect on the total health care outlay would be negligible. Nonetheless, close attention to the rate of fee rise by physicians does indeed indicate a commitment on the part of the physician to maintain health care cost as low as possible.

Probably the area where physicians have the greatest input is in their role as an advocate for the patient. This role becomes increasingly important since it is not the patients that order operations, or tests, or hospitalization—it is the physician. Looking at the area of diagnostic tests, for example, figures from the American Hospital Association show an annual increase of almost twelve percent a year in the number of tests ordered by physicians. Between 1973 and 1976 the increase in radiological procedures was up one hundred and seven percent. This is one area where the physician is totally in control of the decision-making process. As a result we are talking about six billion tests a year, costing twenty billion dollars, and accelerating by ten percent each year. This then becomes the equivilent of thirty tests for every man, woman and child in the United States. Yet there is good evidence to show that this increase in testing has no beneficial effect on patient care whatsoever. Indeed, in New Jersey, studying thirty-five thousand chemical analyses done in two hundred and twenty-five laboratories, only twenty laboratories reported acceptable results more than ninety percent of the time.

In 1979, a study relating the number and type of clinical chemistry tests and their influence on clinical judgement concluded that the chemistry data altered the clinical management only five percent of the time! When the number of tests was arbitrarily limited to eight tests per patient per day, the percentage of chemistry determinations which altered patient care increased to twenty-three percent. As a result the overall workload of the laboratory was reduced twenty-five percent without any demonstrable decrease in quality of the care.

A similarly oriented study in Pittsburgh, reviewing critically patient care on a random sample of routine admissions found it possible to save ten percent of the cost on almost all admissions, and many could have been saved twenty percent or more with no significant change in the basic therapeutic course followed. Thus in 1976, one hundred and twenty billion dollars was spent on personal health services in the United States of which seventy-seven percent or ninety-three billion dollars were generated solely by the actions of physicians. Additional studies are demonstrating that it is possible to improve patient care and reduce direct cost of expenditures for unnecessary, inappropriate, and repetitive laboratory determinations, treatments, diagnostic tests etc. With finite resources, more attention must be given to paring the quality of health care, and increasingly it has been shown to be possible without effect on the death rate or longevity of the population.

It is difficult to argue that there is no fat in the system that is currently in existence. Yet obviously, physician participation is not the sole answer, and I would not suggest for a moment that physicians should take the rap for much of what is beyond their control. What I am suggesting is that, if the profession will demonstrate its own deep dedication to controlling costs, it will gain creditability with the government and public, as it points out the defects in society leading to heightened use of scarce resources. The profession with its own house in order must speak out on the societal issues as well. Among these should be listed: 1) The distinction between the right to health and the right to health care, with the notion that with rights come responsibilities, 2) Alteration of lifestyles leading to a healthier population. With the decrease of the speed limit to fifty-five miles per hour, there was a fifteen percent drop in morbidity and mortality from highway accidents. All of this occurred without a single new medical achievement, and suggests that the way to reduce death on the highways is not to build hospitals every mile, but to build better roads, better cars, and better drivers. We all know the dangers of alcohol, and it is estimated that two-thirds of the murders, one-third of the suicides and one-half of the accidents that occur in this country involve alcohol to a significant degree in one fashion or another. Physicians are well aware of the excessive use of hospital resources as a result of complications of alcoholic liver disease. Tobacco also needs to be mentioned since ninety percent of all lung cancer and emphysema can be clearly linked to cigarette smoking. Smokers account for eighty-eight million more days of sickness a year than do non-smokers.

Certainly industry and business have a great role to play in controlling health care cost, and there are some very clear alternatives to the bottomless pit that many industries see in their health care expenses. Perhaps the greatest role for industry is to realize the great stake they have in the health of their employees and their control over these employees. The president of one midwestern company summed it up best when he said, "The financial health of our company is directly related to the physical health of our employees." He pays his workers four dollars for each pound of weight they lose in an ongoing physical fitness program. At Sun Valley Executive Health Institute, scores of highly paid company executives attend seminars on how to combat stress, cut down on drinking, and eliminate other bad habits. In North Carolina, Cannon Mills, through a cancer screening program found twenty cases of incipient cancer, the treatment of which cost only ten percent of what it would have cost had the malignancy spread before discovery. There is literally no limit to the potential of industry and labor to reduce health care utilization and cost. Together with physicians, industry and labor could develop educational programs related to appropriate utilization of health care services and facilities.

In addition, the profession should be much more vocal in speaking out about the need of education in secondary schools, colleges, medical schools and even in continuing medical education courses for physicians on the economics of health care. The American public must also be made aware of the fact that they spend more than four billion dollars a year on pure quackery alone. In this list is not even included the problems of the environment, occupational health, and other areas that are clearly manipulable outside of medicine itself, and for which great benefit could be derived without the need for one new medical intervention.

And lastly the profession must point out to the public the cost of unreasoning bureaucracy which is adding at least twenty-five percent to the cost of health care in this country.

The reduction of health care expenditures is limited only by the ingenuity of those addressing the issues. So far a great deal of discussion and bantering of statistics has occurred, but what is lacking is a commitment to do something about the problems that everyone acknowledges exist. Tim Norbeck, the executive director of the Connecticut State Medical Society, expressed it well when he wrote, "I believe that the individual's attitude toward rising health care costs and toward the energy crisis are very similar. We all know what we should do but have little motivation to do it. Even after the American people became acutely aware of the energy crisis, they demonstrated a stubborn reluctance to cut back on waste and reduce consumption. Raising the price of a gallon of gasoline is not going to inhibit consumption any more than escalating health care cost will induce people to take better care of themselves. People are going to 'do their thing' unless there is a financial incentive of considerable magnitude to encourage them to do otherwise."

Going further, Mr. Norbeck points out that such negative incentives could work hardship on millions of Americans already in a marginal health care economy.

When you realize these words were written in 1977, and how little the sound and fury have abated, the magnitude of the problem and the illusiveness of its solution are apparent. With so many competing groups, all trying to protect their parochial interest, (and the medical profession is no exception) the politics of change soon becomes the policies of inaction. Unable to satisfy anyone, we drift, unable to deal with cost containment or indeed of any issue of national magnitude.

I firmly believe that the medical profession has a scientific and moral obligation to establish priorities in health care, to provide efficient, effective, economic, safe care, and to speak out against those practices to the contrary. We really don't have too many options left. Either we increase self-regulation and self-restraint, or health care costs will continue their inexorable rise and the system will bankrupt itself leaving us all government employees. It is essential that we as a profession reconsider current practices and concepts that affect health care costs. We need to re-evaluate the use of outpatient treatment, to question the balance of new technological advances and equipment versus their cost and proven benefit, and to re-define what we mean by accessibility in the delivery of health care. Perhaps, most of all, we need to become more positive and vocal about the responsibility of individuals to maintain their own health, to adopt more positive lifestyles, and we need to educate the public about the factors influencing the cost for health care. It must be communicated that health care alone will never guarantee good health.

These are only suggested beginnings, and should not be considered conclusions. Changes in society and its problems will continue, and we should expect the health care industry to respond to new situations as they occur.

Why should physicians be interested in cost? Simply because today the very future of the profession and its ability to provide quality health care for all at a cost all can afford depends upon our response to this challenge of health care expense. What we do as a profession will become increasingly important, and may well determine the ultimate outcome. It does not mean we will succeed, but it does oblige us to try.

THE JCAH NAMED AN AD HOC COMMITTEE TO STUDY CRITICISM directed at the organization by the AMA and the American Hospital Assn. Complaints about the operation of the hospital accrediting body were made recently in meetings of the house of delegates of the two parent groups. Other JCAH parent groups are the American College of Physicians, American College of Surgeons, and American Dental Assn.

AMA and AHA reports and resolutions were referred by the JCAH Board of Commissioners to the new ad hoc committee for "immediate deliberations and recommendations" and a report no later than December. Criticism of the JCAH includes ambiguous standards, repetitious administrative activities, arbitrary interpretations of standards by on-site evaluators, lack of flexibility for individual hospitals and medical staffs.

A commissioner from each of the JCAH parent organizations is included on the ad hoc committee, as well as the chief executive officer and the chief elected officer of each group. Commissioner members are Ceylon Lewis, MD, American College of Physicians, chairman; Daniel T. Cloud, MD, president-elect of the AMA; Frank Stinchfield, MD, American College of Surgeons; Horace Cardwell, a Texas hospital administrator, AHA; and Horace McCallum, DMD, MD, American Dental Assn.

In another action, the JCAH board changed a requirement that had mandated cardiopulmonary resuscitation training for all members of hospital medical staffs. The revised requirement, effective immediately, reads: "Staff members should be encouraged to participate in pertinent self-assessment programs and in basic cardiopulmonary resuscitation training." A JCAH spokesman said the change was made because of concerns expressed by practicing physicians. "JCAH is continuing a long-standing policy of reviewing recommendations from the health care field," he said. "It's crucial that JCAH maintain this flexibility and responsiveness."

—AMA *Newsletter,* Vol. 12, No. 28, August 25, 1980

Month in Washington

The Professional Standards Review Organization (PSRO) program for Medicare-Medicaid should be allowed to develop to its full potential, the American Medical Association has told Congress.

The medical profession has accepted PSRO as a quality assurance program. "Therefore, we feel that it is inappropriate to evaluate the program solely based on a measure of dollars and cents."

Alan Nelson, M.D., a member of the AMA Board of Trustees, told the House Ways and Means subcommittee on Health that the PSRO program is a successful example of cooperation between the medical profession and the federal government. Some 167,000 physicians are participating, Dr. Nelson noted.

One of the problems with PSRO since its inception in 1972 has been the tendency of administrations, Democratic and Republican, to eye the program as one strictly designed to save money. There have been crisis points in recent years when PSRO was believed to be in jeopardy because of high-level belief that it was costing more than it was saving.

Dr. Nelson pointed out to the subcommittee that the PSRO law declares it is designed to "promote the effective, efficient and economical delivery of health care services of proper quality."

There have been numerous analyses in recent years of the cost-effectiveness of PSRO. The two most recent, by the Health Care Financing Administration (HCFA) and the Congressional Budget Office (CBO), used the same data base but reached opposite conclusions. The CBO said PSRO's were not cost effective. HCFA said that in fiscal year 1978 they saved $21 million.

"Because of this divergence in interpreting the PSRO program data and the fact that PSRO effectiveness should be reviewed by means other than just cost-effectiveness, the AMA views such single directional analysis as impractical," said Dr. Nelson. The matter is especially critical now, he added, because the Health and Human Services (HHS) Department has started to terminate PSRO's that it deems to be "poorly performing and cost-ineffective."

It is premature to attempt to measure the cost-effectiveness of the PSRO program, Dr. Nelson said; adding that "the PSRO program has been consistently underfunded, with some PSRO's not even receiving all of the funds necessary to properly design and subsequently implement the sophisticated review and data collection operations essential to conduct a proper review program. Until the program becomes fully operational, it is a mistake to attempt to ascertain its cost-effectiveness."

The AMA witness also urged Congress to guarantee the confidentiality of PSRO information. "The effectiveness of the PSRO program is inextricably linked to its ability to preserve the confidentiality of patient, physician, and hospital profiles."

The AMA also recommended a provision that would subject services performed by or in federally-operated health care institutions to PSRO review and to provide for a more effective administration of the program. The AMA-developed amendments to the PSRO law were recommended.

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Congress this year is nearing final action on a major extension and expansion of the community mental health center program.

The House recently approved a four-year extension authorizing federal aid of $78 million next fiscal year, climbing to $200 million by 1984. The states would play a greater role than at present. The Senate has passed a more generous measure.

A controversial patients bill of rights provision was deleted in the Senate bill. The House measure did not contain such a provision.

The bill, approved 277-15, involves the states more fully in the planning and provision of community mental health services in hopes of attracting more state funding.

New special grant categories were established for services to the chronically mental ill and for disturbed children. Another new program would deal with providing services within ambulatory health care centers.

Funding would be provided for services to those groups that state and local health planning agencies find to be underserved or unserved. The states, through local planning processes, will determine which groups in which areas are in need of special attention.

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The big money bill for the Department of Health and Human Services' operations next fiscal year has finally started moving through Congress. The $57.1 billion approved by the House was $336 million less than the Administration requested.

By and large, the lawmakers went along with the strict economy budget prepared by President Carter's

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Prepared by the Washington, D.C.
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budget men. The interest in the congressional actions centered for the most part on how individual programs fared. Congress made clear earlier that it was in no mood to add significantly larger sums to the bare-bones money requests.

Some key programs were not listed in the House appropriations bill, including health education and the national health service corps, authorizations for which are proceeding on a separate track with appropriations to follow.

Running down the major HHS breakdowns and comparisons with budget requests:

Public Health Service $6.7 billion	+ $162 million
Health Care Financing Administration (Medicaid) $26 billion	− $ 21 million
Social Security Administration (Medicare) $19 billion	− $400 million
Human Development Services $5.3 billion	− $ 68 million
Under the PHS:	
Health Services Administration $1.2 billion	− $746,000
Center for Disease Control $329 million	+ $ 36 million
Nat. Institutes of Health $3.6 billion	+ $126 million
Alcohol, Drug Abuse and Mental Health $1 billion	− $1.4 million
Health Resources Administration $168 million	+ $14 million

PHS programs receiving slight boosts include family planning, state health service grants, maternal and child health, NIH research activities, drug abuse and health planning. Decreases were suffered by alcoholism, community health centers, home health services, mental health, health maintenance organizations, and professional standards review organizations.

With respect to HMO's, the Appropriations Committee noted that the program was having difficulty spending its current budget and could end the fiscal year "with a fairly large carryover balance on hand."

The report continued:

"The committee has received information about the increasing number of federally funded HMO's which are having difficulty reaching the breakeven point, and which are not in compliance with federal qualification guidelines. A number have defaulted on their federally guaranteed operating loans. The committee is concerned about the way the department establishes new plans in geographic areas where HMO's already exist.

Two of the major HHS initiatives heading into the 1980's were supposed to be major new emphasis on health education and alcohol abuse programs.

The committee's handling of these programs underlines how far they have dropped out of sight as a result of the economy push and possibly a change of mind in the administration.

Health education got $13.7 million, only the amount requested and only a continuation of the funding for the current year.

Alcoholism fared worse. The project grant request for the National Institute on Alcoholism and Alcohol Abuse was slashed by $35.3 million and new funding to implement special alcohol initiatives next year was eliminated.

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The tools economists employ to assess cost-benefit ratios are of limited value in health care, the Congressional Office of Technology Assessment (OTA) has conceded. An OTA report frankly discussing shortcomings as well as strengths of economic standards for health care came as something of a relief to the health professions, since the OTA and a federal agency (the National Center for Health Care Technology) have been viewed with misgivings by the medical profession. The fear has been that strictly economic judgments could be used to discourage valuable technological and other medical methods, such as CAT scanners.

An OTA report on the implications of cost-effectiveness of medical technology says the results of CEA and CBA studies "should not be the primary determinants of any decision concerning health care." Contrary to some expectations, the report adds, the use of CEA/CBA, by itself, "will not be an effective tool for reducing or controlling overall expenditures for medical care."

However, the OTA asserts that the process of explicitly analyzing costs and benefits "can lead to better decisions in health care, and interest in the use of CEA/CBA is likely to increase substantially."

Senator Edward Kennedy (D,Ma.), chairman of the Senate Human Resources Subcommittee on Health, said "limitations on resources require that the benefits of medical technologies be weighed against the costs." He said the report "underscores my belief that the simplistic use of cost-effectiveness analysis will not resolve many of our basic dilemmas in health care delivery."

Cost Benefit Analysis involves expressing both costs and benefits in dollars, resulting in a net plus or minus dollar figure or in a numerical ratio.

Cost Effectiveness Analysis differs in that costs are expressed in dollars but effectiveness is measured in non-monetary units such as lives-saved or life-years-gained. Both CEA and CBA are designed to integrate the economic and health aspects of decisions.

The nation last year spent an estimated $212.2 billion for health care, 12.5 percent above 1978, the government has reported.

The 1979 health spending amounted to an estimated $943 per person, of that amount, $406, or 43 percent, represented public spending.

The latest comprehensive health spending estimates were compiled by the Health Care Financing Administration (HCFA) and show that outlays by Medicare and Medicaid amounted to $29.3 billion and $21.7 billion respectively, combining to pay for 27 percent of all personal health care in the nation. Benefits for hospital care alone amounted to $29.7 billion for both programs.

Highlights:

**Expenditures for health care included $54.4 billion in premiums to private health insurance, $60.9 billion in federal payments and $30.5 billion in state and local government funds.

**The $85.3 billion bill for hospital care represented 40 percent of total health care spending in 1979. These expenditures increased 12.5 percent over 1978.

**Spending for physician services increased 13.4 percent to $40.6 billion—19 percent of all health care spending.

**All third parties combined—private health insurers, governments, philanthropic and industry—financed 68 percent of the $188.6 billion in personal health care in 1979, ranging from 92 percent of hospital care services to 64 percent of physicians' services and 39 percent of the remainder.

**Direct payments by consumers reached $60 billion in 1979. This represented 32 percent of all personal health care expenses.

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The Defense Department is confident it can handle physical exams in case of a draft without having to seek the aid of civilian physicians.

The number of military and recently-retired military physicians are "more than adequate" to handle the job, a spokesman said. The recently retired group (about 300) are subject to call-up in event of a national emergency.

Draft physicals would be carried out in 67 Armed Forces Examining and Entrance stations across the country and in Hawaii, Puerto Rico and Alaska. Draftees who passed the physicals could be inducted immediately.

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Legislation was introduced in the House to prohibit federal reimbursement under the Medicaid program for drugs that have not been found effective by the Food and Drug Administration. Rep. Bob Eckhardt (D, Texas), chairman of the House Commerce Subcommittee on Oversight, said as much as $400 million has been "wasted" over the past 10 years on such drugs.

The Kaiser-Permanente medical care program has assumed management and financial responsibility for Georgetown University Community Health Plan, which has been renamed Kaiser-Georgetown Community Health Plan, Inc.

The Georgetown Plan provides medical and hospital care on a prepaid basis for about 54,000 members in the District of Columbia, Maryland, and Virginia. Kaiser-Permanente is the nation's largest group practice prepayment health care delivery system. Most of the operations have been on the West Coast with the exception of Cleveland, Ohio.

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Illicit drug use has increased sharply in the past 20 years, according to two studies for the government.

The proportion of people who have used marijuana has increased from four percent to 68 percent. Harder drugs—cocaine, heroin, hallucinogens, or inhalants—have been tried by 33 percent of 18 to 25 year-olds.

The studies show that between 1972 and 1979 experience with marijuana and cocaine has doubled among young teenagers and among those over 25 years of age. Between ages 18 and 25, cocaine use has tripled and marijuana use has increased from 48 percent to 68 percent.

The illicit use of stimulants, sedatives and tranquilizers reported by 12 to 17 year-olds and those over age 25 has remained relatively constant over the last decade. However, these drugs showed large increases by 18 to 25-year-olds until 1977. Experience with heroin has been constant during the 1970's with about three percent or less, reporting they have tried it.

The President's Page

Until now, Connecticut physicians have been fortunate in the cost and availability of professional liability insurance. The contract with Aetna negotiated a decade ago by Fred Fabro and the Committee on Insurance has made insurance available to all Society members. Low costs have been due in part to a favorable climate, statutes of limitation and to very favorable premiums. It was inevitable that the explosion in liability costs, which has beset most of the nation in the past decade, would reach Connecticut. Here, in the past two years, both the instance and cost for suits have doubled.

Future prospects are not good. Rates in Connecticut have not been high enough to guarantee Aetna a reasonable return and we will be paying more in the next five years to make up for this. More complex medical care resulting from rapidly increasing knowledge and skills and, necessarily, more specialization in medicine will not only produce more miracles of cure but will result in more poor outcomes due to attacking diseases before considered unconquerable. Increasing skills and successes of plaintiffs' attorneys and the attractiveness of great profit will not work to reduce suits. The broadening of the definition of liability from negligence and incompetence to include poor outcome, the rising legal definition of standards of practice, and changing jury attitudes towards compensation, all promise increase in professional liability costs.

The Society has been quite active in this field. Along with guaranteed insurance for members negotiated with Aetna came the advisory panels on which many members have served. This service has been an education for panelists and a successful means of reducing baseless suits. Education through county societies increased awareness of the causes of liability among those members who attended the meetings. The Patient Injury Prevention (P.I.P.) program, in the process of organization this past year, will receive from Aetna information about all suits in Connecticut. This will be reviewed and passed on to all physicians, particularly through hospital staffs since some 80% - 90% of suits originate in the hospital setting. Educational programs will also be developed and presented at local societies, hospitals and through our journals and mailings. Further legislation will be presented this year, perhaps leading to a better system of compensation with some limitations of physician liability. Aetna is planning, with our support, a vigorous defense in every defensible case to discourage plaintiffs' attorneys in doubtful cases.

None of these efforts will be effective without the support of all 4,000 members and the Auxiliary. Physicians and their spouses must call and write the legislature and attend hearings. Physicians must all participate fully in the P.I.P., including careful reading of journal articles and mailings. Physicians must willingly serve on panels and as witnesses. The Society has also been investigating the feasibility of a physician-owned liability company. There seems to be a possibility of significant premium reductions. All physicians should watch these developments carefully to be able to make intelligent decisions when and if such a plan is formulated.

By persistent and concerted effort, we may be able to limit somewhat the excessive cost of professional liability as well as reduce injuries to patients; we must do our best in this direction. However, the professional liability system is so socially indefensible and inefficient that some modification must be sought. The high costs of medical liability are borne by the ill and disabled through the necessary increases of physician and hospital charges. Less than 40% of premiums go eventually for relief of the injured (an average of five and one-half years after an injury occurs!). Insurance premiums force older physicians into early retirement. Young physicians must consider alternatives to private practice in some of the more complex and difficult specialties. Costs of medical care continue to rise as insurance forces physicians to increase fees by an average of 5%, and hospital costs nearly 1%, in addition to inflation.

The system is expensive, inflationary, inefficient, unjust, unfair and cumbersome. It will become worse. We must change to a system which will compensate *all* injured at fair rates, within a reasonable time, and financed equitably.

W. Raymond James, M.D.
President

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LIFE & CASUALTY

Reflections from the Dean's Office

Honoring the Conventions

ROBERT U. MASSEY, M.D.

During this past summer, the press reported a flurry of misdemeanors that raise questions about the honesty of the scientific community. There are in these reports implications not only of dishonesty but also of venality, irresponsibility, and even witlessness.

There was a disclosure of falsified data by a cancer research team at University Hospital in Boston; the *Globe* ran a five-part series[1] and concluded that the response of the scientific community, especially the granting agencies and administrators, may have been unusually gentle and restrained.

Science[2] reported plagiarism in five papers by the Jordanian, Dr. Elias A.K. Alsabti, who made a whirlwind career through several American academic institutions before ending at the American University of the Caribbean, where he received his M.D. degree. Plagiarism and falsification of data have been alleged against a former junior investigator at Yale, and questions relating to the responsibility of laboratory and institutional heads in these instances have been raised. The removal of a co-author and colleague's name from an article without his consent was attributed to a senior author, a former faculty member of the University of Connecticut, in a recent letter to the *Lancet.*[3]

When these things come to light, there is an inclination toward self-righteous surprise to find in science what one suggests he would expect in public life, observing at the same time that one does not wonder given the general decline in public and private morality.

Morality has always been declining, according to contemporary writers, since the days of the ancient Greeks and Hebrews. It is an assertion difficult to prove, but history does suggest that, like the market, morality has its ups and downs. Certainly our forebears in science and medicine have not always been exemplary.

When Galen wrote that the pig's squeal returned when he reconnected the severed recurrent laryngeal nerve, he was cooking his data. Plagiarisms were common until very recent times, and the stealing of ideas was the way to get ahead. Thomas Browne's *Religio Medici* was first published without his consent.

I suspect the mean morality of scientists is as high as that of any professional group, and in the matter of truth telling, higher. This is not because scientists are better people, but because science cannot work with falsehood; it rests upon verifiable reporting of objective data, and lies are readily found out. An editorial in *Nature,* after reminding its readers that scientists in the past were not without their misdemeanors, continues:

> "In a small part, the conventions by which the scientific profession now regulates itself derive from the bad experiences of these early days. The object of the convention is to give truth an overwhelming advantage over falsehood, originality a powerful edge on repetitiveness and to make it possible that people whose contributions to the stream of discovery are very different are nevertheless able to work easily alongside each other. The scientific community should count itself lucky that these conventions are now so deeply ingrained, so widely respected and so infrequently dishonoured."[4]

The conventions, of course, are truth telling and giving credit. Both are moral issues, as are considerations of public interest and taking special pains in making observations. But for science, truth telling and giving credit make up the main strategy, and scientific progress is not possible without them. In politics, revealing and withholding information may be part of a strategy for success; the lawyer may select and order facts so as to complement his eloquence; the theologian may find his data in sources hidden from others; but the scientist works in full sunlight with objects which his colleagues also can see and with logic which he invites others to test. He may make errors in observation, or he may reason badly; he or someone else will straighten him out. If he tells an untruth or claims for himself an idea that is not his, discovery is not long in coming. As the editorial writer in *Nature* says, "Plagiarists are either fools or desperate people."

Ethical behavior may be no more than behavior with survival value; the social biologists have suggested that. There might even be genes for it. If we believe, however, that the good will inherit the earth, our short history has been disappointing; but there is no doubt about who inherits the rewards of science.

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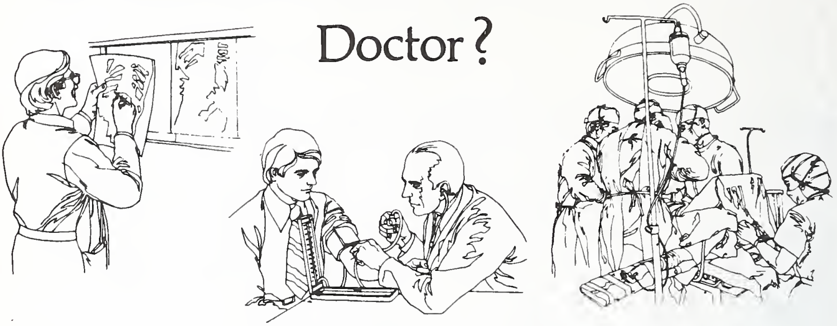
ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.



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Informed Consent: Disclosing the Risks of Refusing Treatment

JOSEPH M. HEALEY, J.D.

Physicians have a legal obligation in most situations to obtain voluntary, competent and informed consent from their patients before commencing treatment. Of the three dimensions of consent, by far the most frequently problematic aspect is the informed dimension. Connecticut is one of the relatively few states whose Supreme Court or legislature has not attempted to formulate the legal obligations of physicians in this difficult and complex area. We in Connecticut look to other jurisdictions to keep abreast of developments which might indicate the future of Connecticut law. Of particular interest in this regard is a recent California case dealing with disclosure of risks to a patient refusing proposed treatment.[1]

The defendant, Dr. Claude R. Thomas, is a family physician engaged in general medical practice. He acted as the primary physician for Rena Truman and her two children from April, 1963, until March, 1969. Though many of the details of the relationship were the subject of dispute at trial, it is clear that a gynecologist-consultant who examined Ms. Truman in October, 1969, discovered that she had cervical cancer of an advanced stage. The tumor was too far advanced for surgical removal and was unsuccessfully treated by other methods. Ms. Truman died in July, 1979, at the age of 30. Her children filed a wrongful death action, alleging that Dr. Thomas had negligently caused the death of their mother by failing to perform a pap smear. Although Dr. Thomas saw Ms. Truman frequently during the six-year period, he conceded that he neither performed a pap smear test nor informed Ms. Truman specifically of the risk involved in failing to undergo the pap smear. He testified that he regularly informed her that she should have a pap smear as part of a complete examination. On at least two occasions, he claimed that Ms. Truman refused on financial grounds and that she refused his offer to defer payment. He claimed also that she asked him on other occasions to put off the test until her next visit. However, Dr. Thomas' medical records contain no reference to any discussion or recommendation that Ms. Truman undergo a pap smear. Dr. Thomas himself during the trial was unable to describe specific conversations with Ms. Truman. The jury rendered a special verdict in support of Dr. Thomas, refusing to find him guilty of negligence. An appeal followed.

Ms. Chief Justice Bird, writing for the majority of the Court, concluded that the central issue of the case was whether Dr. Thomas breached his duty of care to Ms. Truman by failing to inform her of the potentially fatal consequences of allowing cervical cancer to develop undetected by a pap smear. Under the prior California consent case,[2] the physician was required to disclose to the patient sufficient knowledge to allow the patient to make an informed choice. This includes all material information defined as that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure. Excluded from this requirement would be information which is commonly appreciated. The *Cobbs* case required that patients be told the material risks of the procedure, the risks of a decision not to undergo the procedure and the probability of a successful outcome. Ms. Justice Bird rejected Dr. Thomas' claim that he has obligations to disclose risks only when the patient consents. The *Cobbs* case requires disclosure even when the patient refuses. Dr. Thomas' second argument—that the risk from cervical cancer was remote and commonly appreciated to be remote—was likewise rejected by the Court, since there was insufficient evidence that either a reasonable person should be aware of the risk or that Ms. Truman herself was actually aware of the risk. After reviewing several issues of claimed instructional and evidentiary error, the Court ordered a reversal of the trial court decision.

In deciding this case, the sharply divided California Supreme Court (4-3) reminds us that there is significant difference of opinion in our society about the respective rights and duties of both provider and patient. A major tenet of the patient rights movement is that the imbalance of power in the doctor-patient relationship must be reconsidered. The *Truman* case furthers that process but in a way which is sure to generate further controversy and discussion.

JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

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The Nature and Rights of the Catholic Hospital

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There are over 600 Catholic Hospitals in the United States, housing almost one-third of all non-governmental hospital beds in the country. Catholic Hospitals are unique in their historical origins and in their fidelity to a Catholic code of ethics.

In the State of Connecticut are five Catholic Hospitals: St. Vincent in Bridgeport, St. Joseph in Stamford, St. Francis in Hartford, St. Raphael in New Haven, and St. Mary in Waterbury. Together they house 2,130 beds, or 20.3% of all non-governmental hospital beds in the State. These Catholic Hospitals account for 25% of total inpatient days in the State.

Why does the Catholic Church sponsor hospitals? What is the difference between a Catholic Hospital and another community health care facility? Because of current developments in health care, we Catholic Bishops of Connecticut see a need to underscore the very reasons for existence of a Catholic Hospital. We do this particularly for the benefit of health care planners who may not understand why the Church has Catholic Hospitals.

We see the Catholic Hospital as a means for exercising the healing work of Christ. There is a healing mission of the Church—the corporal and spiritual works of mercy—to which the Church gives witness particularly through her hospitals. The Christian values underlying that healing mission are set down in the preamble of the *Ethical and Religious Directives.* They include three factors or values: (1) the sacredness of life; (2) the meaning of suffering and death; (3) the need to care for the poor.

The Church sponsors Catholic Hospitals so that they may witness before the community to these particular Christian values. The Catholic Hospital then is obligated to witness to the sacredness of life. It is obligated to deliver health care within a Christian context, in the spirit of the Gospel.

A current threat to the Catholic Hospital comes from some governmental health care planners and regulators who view all hospitals as identical and who are moving to consolidate area health care facilities and departments solely on the basis of money. Governmental health care planners and regulators (of whom there are over 60 in number) are laudably concerned with reducing the costs of health care and obtaining the best care for the most people at the lowest price. But governmental health care planners are wrong if they are concerned only with the bottom line—if they are motivated by a utilitarian and pragmatic ethic which attempts to override the rights of the individual American and the rights of a hospital to follow its moral code and to be a witness to the sacredness of life.

We, therefore, will not supply "full services" in Catholic Hospitals if the term includes abortion, sterilization, and other medical practices contrary to our code of ethics or religious needs.

We, therefore, will vigorously defend the freedom of conscience of the Catholic Hospital as a moral person, so that it will continue operating by its moral code and continue witnessing to the sacredness of all life.

We, then, will also vigorously defend the continued existence of obstetrical and gynecological departments in our Catholic Hospitals as needed special witnesses to the sanctity of life from its earliest stages of development.

We, then, will tenaciously guard the right of every citizen to seek health care in an institution that has a code of ethics based on the moral law, an institution dedicated by policy to the preservation of life and the sanctity of the human body.

In our nation, the incorporated, voluntary, non-profit hospital is a legal person. As such, it enjoys, among other legal prerogatives, the constitutional rights of privacy (4th Amendment), due process, and equal protection of the law (5th and 14th Amendments). Therefore, the Catholic Hospital should, fully within its rights, continue its witness to the sacredness of life, to the meaning of human life, suffering and death, and to the care of the poor in our American society.

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EDITORIALS

The Commission on Hospital and Health Care and CT Scanning

The Commission on Hospital and Health Care (CHHC) contends that cost effectiveness should determine the allocation of new medical technology. Yet it ignores the abundant evidence that CT can produce substantial savings (1) by reducing the number of other diagnostic radiologic procedures (some of which are invasive and risky), (2) by eliminating the need for a number of laparotomies and thoracotomies, and (3) by making possible a modest, three to four percent increase in the cure rate of cancer due to improved treatment planning. In the case of The Hospital of St. Raphael, it is estimated that the annual savings would approximate $300,000.

Even so, cost effectiveness is only one of several factors which should influence the allocation of new medical technology. Ethical, moral and scientific issues are also vitally important considerations in a democratic society where every human life has infinite value. Perhaps the publicity generated by Governor Grasso's excursion to Bridgeport recently for a body CT scan will influence the CHHC to change the irrational policy which has resulted in a maldistribution of CT body scanners.

The public has not been told that the purchase and operating cost of all CT scanners in the United States constitutes less than one percent of the total annual health bill and only five to eight percent of all diagnostic radiology costs.[1,2] Although unnecessary, repetitive, "little ticket" laboratory tests comprise a far greater cost,[2] the CHHC continues to treat CT scanners as a political football and exhibits little interest in dealing with more seminal problems. In the final analysis, the major unnecessary cost associated with CT scanning may well be the substantial monies spent by the regulatory agencies to design and implement their restrictive policies.

Unfortunately, there is considerable confusion among planners and regulators concerning diagnostic testing and therapy. It is unfair to criticize CT because there is no effective cure for many types of cancer and strokes today. It is also unfair to ignore the fact that early correct diagnosis of these diseases can decrease morbidity and improve the quality of life. Surely these worthwhile benefits properly concern the conscientious physician and his patients as much as prolonged survival. Could this money be better spent on prevention? To date, campaigns against smoking tobacco, drinking alcohol, and speeding on the highways have had little effect on changing the American lifestyle. It clearly makes sense to spend a small fraction of the total annual health bill on CT which can facilitate early, accurate diagnosis.

As stewards of the public's health, it is our duty to provide all members of society with ready access to the many medical advantages of CT scanning. Toward this end, we must educate our patients and inform them of the adverse effect of the Commission's present policy on the quality of their health care. Furthermore, we must mobilize both our patients and friends to exercise their political clout. This is the surest, quickest way to abolish the present bureaucratic CT restrictions. In my opinion, the CHHC would do well to follow the example of its equally tough sister Commission in Maryland which recently introduced the enlightened policy of granting certificates of need for CT scanners to all hospitals with 300 or more beds and a busy emergency room.

Robert Shapiro, M.D.
Chairman, Department of Radiology
The Hospital of St. Raphael

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The Adoption of Handicapped Children

Physicians, particularly pediatricians, neurologists, orthopedists and physiatrists caring for handicapped children will be pleased at the achievements of the Connecticut Adoption Resource Exchange of the Connecticut Department of Children and Youth Services which during the last few years has arranged the adoptive placement of several hundred handicapped children whose parents were unable to care for them. Nothing is more distressing for doctors than to care for a handicapped child living in an institution. An institutionalized child, no matter how dedicated the staff may be, suffers the lack of parental care and the feeling of belonging which is only available in a home and family setting. The Staff of the Connecticut Adoption Resource Exchange believe that no child is unadoptable. Their experience reveals that there are many parents who are able to provide love and care in their home for a child with special physical, psychological and emotional needs.

Adults who wish to adopt a child whose parents are unable to provide for his care offer a home and family to a child who otherwise would be rootless and in limbo. Individuals who choose to adopt a handicapped child realize that every child needs to be loved and appreciated for his achievements. They appreciate and enjoy the manner in which youngsters with special needs respond to devoted parental care by gaining confidence in themselves as they mature in their own unique way.

Adoptive placement is best arranged after careful and thoughtful case work discussions with adoptive applicants. The nature and aspirations of potential parents merits thoughtful consideration. When the placement concerns a child with handicaps, detailed discussions with the adoptive applicants, social workers, and medical consultants are important in order to clarify the extent of a child's handicap, the nature of his anticipated development and the medical and educational requirements in the years ahead. Medical subsidy is often available when prolonged and complicated medical treatment is necessary.

It is important to consider carefully the effects on the various family members of the placement of a child with special needs. Sentimental pity is an unsound motivation for adopting a child with special needs. Successful placement of these children requires that parents have unusual patience. While sharing the child's awareness of his imperfection, parents who adopt a child with handicaps need to have the capacity to rejoice in his success and enjoy the natural exchange of love and devotion which is the basis of happy family life. These families see a child where others may see a label; they see a family where others see an institution; they see hope and satisfaction where others see only hopelessness and dismay. They look forward to the satisfaction of providing a home and hope for a child who otherwise would remain in an institution.

Physicians and families seeking further information about adopting children with special needs may obtain it from Connecticut Adoption Resource Exchange, Department of Children and Youth Services, 170 Sigourney Street, Hartford, CT.

Morris A. Wessel, M.D.

Clinical Professor of Pediatrics
Yale University School of Medicine

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membership in The Society, except that they shall not be eligible to vote or hold office. Student Members shall pay no dues.

PROPOSED AMENDMENT

ARTICLE IV. Section 5

Repeal the present Section 5 in its entirety, and replace it with the following:

ARTICLE IV—MEMBERSHIP

Section 5. STUDENT AND POSTGRADUATE PHYSICIAN MEMBERS

Par. 1 Any person whose legal or family residence is in the State of Connecticut and is a regularly enrolled student and a candidate for the degree of Doctor of Medicine in an accredited medical school, as provided in Section 20-10 (Rev. to 1979) of the General Statutes of Connecticut, or any person who is a student in an acceptable medical school located in the State of Connecticut may become a Student Member of The Society.

Par. 2 Physicians who are serving in postgraduate training in hospitals or medical schools in Connecticut may become members of the Society.

Par. 3 Membership shall be obtained by applying to The Society on a form provided for that purpose. A person eligible for student and postgraduate physician membership in The Society becomes a member upon receipt and approval by the Executive Director of The Society of dues prescribed by The Society unless he or she is exempted from payment of dues as provided in Article XII.

Par. 4 Such members shall enjoy all the rights, privileges, and responsibilities of membership in The Society, except as may be specifically set forth in these Bylaws.

ARTICLE V—HOUSE OF DELEGATES

Section 2. COMPOSITION

Add a new subparagraph (d): delegates elected by the student members and postgraduate physician members according to the apportionment provided in Section 4 of Article V of these Bylaws.

ARTICLE V—HOUSE OF DELEGATES

Section 3. ELIGIBILITY

Amend this section by adding the underscored portion to the present text, so that the new Section 3 will read: In order to be eligible for membership in the House of Delegates *except as a delegate elected by the Student Members or Postgraduate Physician Members,* a physician must have been an Active Member or Life Member of The Society for at least the two years immediately preceding the session of the House in which he is to serve.

ARTICLE V—HOUSE OF DELEGATES

Section 4. APPORTIONMENT

Add a second paragraph as follows:

The number of delegates from the Student Members shall be one delegate and one alternate from each medical school in the state. The Postgraduate Physician Members shall be entitled to send from their constituent membership to the House of Delegates each year one delegate for every seventy, or fraction thereof of the number of members as recorded in the office of the Executive Director of The Society on December 31 of the immediately preceding year.

ARTICLE V—HOUSE OF DELEGATES

Section 5. REGISTRATION - Par. 1. CERTIFICATION

Add a second paragraph as follows:

Before every session of the House of Delegates the Student Members and Postgraduate Physician Members shall deposit with the Secretary of The Society a certificate or list signed by the president, secretary, or duly authorized representative of the Student Members and the Postgraduate Physician Members, respectively, or the Executive Director of the Society, listing those members entitled to be seated in the House of Delegates.

ARTICLE V—HOUSE OF DELEGATES

Section 5. REGISTRATION - Par. 1 VACANCIES

Add a second paragraph as follows:

When an elected delegate or the elected alternate from the Student Members or Postgraduate Physician Members is unable to attend a specified session, the Student Members and Postgraduate Physician Members may appoint a substitute delegate and alternate delegate.

ARTICLE V—HOUSE OF DELEGATES

Section 12. PROCEDURE - Par. 3. RESOLUTIONS

Amend this section by adding the underscored portion to the present text, so that it will read as follows: Resolutions may be introduced by any Active or Life Member *or Student or Postgraduate Physician Member* of The Society, in compliance with the following provisions:

Amend subparagraph (b) by adding the underscored language:

Component county associations, *or the Student Members or Postgraduate Physician Members,* whose meetings are held later than the thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.

ARTICLE XII—DUES

Section 1. PRESCRIPTION

Add a second paragraph:

Annual dues for Student Members and Postgraduate Physician Members shall be prescribed for the ensuing fiscal year in an amount recommended by the Council and approved by the House of Delegates. Dues shall be an equal per capita assessment upon each Student Member as for each other Student Member, and upon each Postgraduate Physician Member as for each other Postgraduate Physician Member, except that persons who become Student or Postgraduate Physician Members during the latter half of a fiscal year will be assessed one-quarter of the respective annual dues for that fiscal year.

ARTICLE XII—DUES

Section 2. PUBLICATIONS

Add the underscored language at the end of the paragraph:

Membership dues shall include subscriptions to "Connecticut Medicine" and such other publications

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wishes to announce. . . .

the opening of their NONINVASIVE diagnostic computerized vascular laboratories which provide clinical procedures for evaluation of:

1. Extracranial **CE**rebral circulation.
2. Deep **VEN**ous thrombosis.
3. **AR**terial hemodynamics and occlusive disorders in the upper and lower extremities.

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Hartford, Connecticut 06105

Telephone (203) 243-3985

BOOK REVIEW

The Hepatic Coma Syndromes and Lactulose by Harold O. Conn, M.D. and Milton Lieberthal, M.D., F.A.C.P., Williams & Wilkins Co., Baltimore, 1980, 419 pp., $49.00.

You cannot legislate a new layer of cortical gray matter into, or a cirrhosed liver out of, a man.
—*Boston Medical & Surgical Journal,* 131:125, 1894

Conn and Lieberthal have made a significant contribution to the literature of portal-systemic encephalopathy and its treatment. The first 248 pages put in one place an excellent description of the syndrome, its pathogenesis, and a critical review of the various modalities of management that have traditionally been used. In addition, the authors insert an excellent chapter on the inherited hyperammonemic syndromes, a chapter on Reye's syndrome, and an excellent discussion of how to assess mental state. The next 140 pages discuss the place of lactulose in the management of portal-systemic encephalopathy, plus perhaps more than the average internist wants to know of its pharmacology, mechanism of action, and the use of lactulose in other disorders.

The book is easy to read and, in fact, contains so much of the Conn-Lieberthal wit that sometimes one is lulled into the sense that the book is less scholarly than it really is. This book should be in the library of all gastroenterologists and hepatologists and should find ready use as a reference source for other physicians.

Robert Scheig, M.D.

EIGHTH SEMINAR AND WORKSHOP IN ACUPUNCTURE AND PAIN CONTROL

Sponsored by:
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October 31, November 1 and 2, 1980 Barbizon Plaza Hotel, New York City

Accreditation: As an organization accredited for continuing medical education, the New York University Post-Graduate Medical School certifies that this continuing medical education offering meets the criteria for 30 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

Course Description: Chronic pain, including chronic facial pain, is among the most difficult of challenges to confront the practicing clinician. In the management of chronic pain, acupuncture is a most valuable tool when properly applied. This course, presented by authorities who have long been outstanding in the field, is designed to provide an update on the role of acupuncture in pain control, as well as in the clinical applications. Essential information and techniques will be presented for advanced as well as beginner students, and the course will include patient presentations and clinical instruction in the use of acupuncture. The course is approved by the New York State Boards for Medicine and Dentistry for 30 credit hours towards the State Acupuncture certification requirement. For further information and application write:

Shyh-Jong Yue, M.D., Secretary, New York Society of Acupuncture for Physicians & Dentists, Inc., 115 East 61st Street, New York, NY 10021 or call Sandy at (212) 870-6153 Mon. to Fri. 11 AM to 3 PM.

of The Society as are intended for *distribution to all Active Members, Student Members and Postgraduate Physician Members.*

ARTICLE XII—DUES
Section 3, EXEMPTIONS

Amend this paragraph as follows (additions are underscored, deletions are bracketed):

The dues of any member may be remitted by vote of the Council on recommendation of a Councilor or Associate Councilor elected by the respective component association, provided there has been prior remission of dues by that association. Honorary Members, Life Members *and* Associate Members (and Student Members) shall not be subject to assessment of dues, but may be charged for subscriptions to publications, registration fees at scientific sessions, and the like.

ARTICLE XII—DUES
Section 4. DELINQUENCY

Add a second paragraph:

A Student Member or Postgraduate Physician Member is delinquent if his/her dues are not paid by October 15 of the year for which dues are prescribed and shall forfeit membership in The Society if he/she fails to pay the delinquent dues within thirty days after notice of the delinquency has been mailed to his/her last known address by the Executive Director of The Society.

ARTICLE XV—ASSOCIATIONS OF STUDENT MEMBERS AND POSTGRADUATE PHYSICIANS

This article is entirely new.

Section 1 - DEFINITION

The Student Members and Postgraduate Physician Members should meet as associations between forty-five to sixty days prior to the annual meeting of the House of Delegates of CSMS for the purpose of election of officers and delegates to The Society and at such other times as they deem necessary.

Section 2 - BYLAWS

The Student Members and Postgraduate Physicians shall have the power to adopt bylaws that are not in conflict with the Bylaws of The Society. In the event of an existing or apparent conflict, the Bylaws of The Society shall take precedence.

Section 3 - PROCEDURAL RIGHTS

Student and Postgraduate Physician Members shall be afforded all the procedural rights accorded to members of component associations, as set forth in Section 7 of Article XIV of these Bylaws.

ARTICLE XVI AND ARTICLE XVII (Re-Numbering)

The numbering of the Articles dealing with Amendments and Parliamentary Procedure should be changed from Article XV and Article XVI to Article XVI and Article XVII, respectively, to reflect the addition of new Article XV.

COUNCIL MEETING

Thursday, August 14, 1980

Attendance

Present were: Drs. James, Canzonetti, Parrella, Backhus, Mendillo, Hecklau, Kamens, Hess, Friedberg, Van Syckle, Fabro, Cramer, Anderson, Freedman, Doctor, Klimas, Abbot, Seide, Shenker, Tierney and Bobruff.

Also present: Mr. Norbeck, Mr. Sweeney, Mr. Brunell, Mr. Fiorentino, Mrs. Lindquist, Dr. Clare Callan and Mr. Tomat (FCMA).

Replacement for Committee on Mental Health

It was VOTED to appoint Boris G. Rifkin, M.D., New Haven, to the Committee on Mental Health to replace Robert Stubblefield, M.D., who moved from the state.

Nominations to the AMA

It was VOTED to nominate the following physicians for consideration by the AMA to be appointed to six Task Forces which will address themselves to "Future Directions for Medical Education": Orvan W. Hess, M.D., Donald L. Brown, M.D., Lawrence K. Pickett, M.D., James D. Kenney, M.D. and Marvin Garrell, M.D.

Nominees to Connecticut Medical Examining Board

It was VOTED to submit the names of Drs. Charles Zigun, Elwood F. Ireland, Jr., Robert L. Piscatelli, Sister Mary Helene Blakeslee, Orlando Pelliccia, Jr. and Shirley Williams to the Governor for possible appointment to the CMEB.

Request for Appointment of Liaison Committee with Connecticut State Police Department (CSPD)

It was VOTED to appoint Edward A. Kamens, M.D. and Patrick R. Concannon, M.D. as a committee of 2 to meet with the CSPD to determine what the problems were and report back to the Council, following which a more appropriate committee could be appointed, if necessary.

Reports from Physicians Serving on State and Federal Agencies

Verbal reports were made on the various agencies by Drs. Canzonetti, Hess, Fabro, Friedberg and Mendillo. Dr. Canzonetti pointed out to the Council that a written comprehensive staff report on "State and Federal Planning and Regulatory Agencies" had been prepared by Richard J. Fiorentino and that such reports will be available for each Council meeting.

IPA/HMO Discussion

Mr. Peter Aaronson discussed the operation of the New Haven County Medical Association Foundation for Medical Care and mentioned that the Foundation had enrolled 550 MDs and 2000 members up to the present time. He explained that the Foundation expected to be federally qualified by late spring or early summer of 1981.

Mr. John Nelson discussed the Community Health Care Center Plan which is ten years old and has 26,000 members. He also explained that he had become executive director upon Isadore Falk's retirement. In answer to a question, he pointed out that the Plan will be negotiating a medicaid contract in Connecticut but that no HMO in the state presently enrolls medicaid patients. Mr. Nelson mentioned that the CHCP is the only HMO in Connecticut thus far which enrolls medicare beneficiaries.

Mr. Robert W. Doering discussed the Physicians Health Services Plan in Bridgeport and mentioned that, in his opinion, the IPA represented a bridge to the future to keep the practice of medicine in the private sector. He expressed the concern that if physicians did not make a success of their IPA involvement, insurance companies and industry would take over the HMOs leaving physicians with less decision making capabilities. Dr. Doering pointed out that the IPA in Bridgeport had received $608,000 in grants and that each enrolled physician contributed $500.

Report of the President

a) W. Raymond James, M.D., reviewed for the Council his exchange of correspondence with Sally Bowles Rosen, Commissioner of Long Term Care in Nursing Home Facilities and mentioned that Mrs. Rosen may seek an advisory committee from CSMS to assist her in her Commission endeavors. Dr. James advised the Council that he would apprise them of developments as they arise and that he planned to meet with Mrs. Rosen in August.

b) President James reported on his and Mr. Norbeck's recent meeting with Mrs. Czarsty and Dr. Clare Callan of the Auxiliary to discuss Mrs. Czarsty's report to the House of Delegates. He pointed out that the chairmen of the CSMS Committees on Public Health, Legislation, Public Relations and Drug Abuse had been contacted to see if they would object to two Auxilians attending their meetings instead of the present one representative. Dr. James mentioned that all three responses received thus far had been positive. Also to be pursued will be the possibility of Auxiliary and CSMS committees meeting jointly at times.

c) The possibility of adding The Auxiliary dues to the Society's billing is being studied by Mr. Norbeck who will report on this subject to the Council at a later date.

Professional Liability Program

CSMS Vice President and former chairman of the Committee on Professional Liability, Dr. Gioacchino S. Parrella, reviewed for the Council the information released by the Aetna on the new rate increase in professional liability insurance premiums. He mentioned that the Aetna planned to increase the rate by 70% for all classifications and that it was also recommending to the Society a risk management and loss prevention program. Dr. Parrella also pointed out to the Council that the CSMS consultant on professional liability, Mr. John Dorsett of American Health Systems, would have a report available in a few weeks on the situation and a response to the rate increase. Mr. Dorsett was coordinating his report with that of CSMS actuarial consultant, Mr. David Bickerstaff. In view of the forthcoming information, it was VOTED to postpone discussion of the reaction to the rate increase for a special meeting of the Council when the necessary information is available. *NOTE:* A special meeting of the Council has been scheduled for Wednesday, September 17 at 6:00 P.M.

After discussion of the proposed CSMS-Aetna Risk Management-Patient Injury Prevention Plan, which was outlined in a memo to the Chairman of the Council, it was VOTED to approve of the Plan and transmit the details of same to the CSMS Committee on Professional Liability and Continuing Medical Education.

1980 Revisions to the State Health Plan (SHP)

A critique commentary of the revisions to the State Health Plan submitted by the Committee on Statewide Medical Planning and which was distributed to all Council members was reviewed. It was VOTED to adopt the commentary as the Society's position for submission to the State Health Coordinating Council (SHCC) at the public hearings as testimony.

Recommendation from Committee on Statewide Medical Planning

It was VOTED to approve of the recommendation of the Committee on Statewide Medical Planning to authorize the appointment of an Ad Hoc Committee on Membership Promotion to be appointed by the Chairman of the Council as follows (4 CSMS members, 1 student member, 1 resident member, 3 Auxiliary members).

Report on AMA Meeting, Chicago, July 20-24, 1980

The AMA Newsletter dated July 28, '80 which included highlights of the AMA meeting and a summary of actions taken at this meeting, prepared by Mr. Norbeck, were received as information.

Dr. Guy W. Van Syckle reported on the recent AMA Convention with particular emphasis on the newly adopted code of ethics. The code received 195 favorable votes in the House of Delegates, just 11 more than necessary for adoption. (NOTE: The new AMA

Code of Ethics will appear in the September issue of *Connecticut Medicine.*)

Recommendations from the Committee on Statewide Medical Planning RE Liaison with Connecticut Hospital Association

President James informed the Council that the CSMS had been meeting with the CHA on an as needed basis and that the two organizations had worked well together.

After discussion, it was VOTED to receive as information the report of the Committee on Statewide Medical Planning which urged further CSMS liaison with the Connecticut Hospital Association.

Liaison Committee to the State Department of Health

It was VOTED to authorize the Committee on Public Health to select from its membership a subcommittee to act as an ongoing Liaison Committee to the State Department of Health.

Recommendations from the Committee on Peer Review Systems

RE: Guidelines for Medicare Reimbursement for Keratomeliusis and Keratophakia (Refractive Lamellar Keratoplasty)

It was VOTED to approve of the concept that keratomeliusis and keratophakia are developmental procedures which are reasonable and necessary for specific indications as indicated in the protocol submitted by the Committee on Peer Review.

Committee on Peer Review

It was VOTED to add Marvin I. Fox, M.D., New Haven, to the subject committee.

Committee on Statewide Medical Planning

It was VOTED to add John A. Barrasso, M.D., North Haven, to the subject committee.

Committee on Program of the Scientific Assembly

It was VOTED to add Ramon N. Kranwinkel, M.D. of Danbury, to the subject committee for the term 1980-85.

Life Members

It was VOTED to accept for information the following Life Members:

Harold M. Clarke, Avon (H) - 1/1/80
Sidney L. Cramer, Hartford (H) - 1/1/80
William J.H. Fischer, Litchfield (L) - 1/1/80
Joseph B. Forman, New Haven (NH) - 1/1/80
Saul J. Jaiven, Stamford (F) - 1/1/80
James W. Major, Jalisco, Mexico (W) - 1/1/80
Thomas M. Monagan, Waterbury (NH) - 1/1/80
A. Eugene Sirica, Waterbury (NH) - 1/1/80
Stanley J. Weigel, Danielson (W) - 1/1/80

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on August 14, 1980. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

In Memoriam

BAUSCH, CARL P., Tufts University, 1929. Dr. Bausch was an ophthalmologist in the Hartford area since 1932. He was a Commander in World War II from 1943-1946. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Bausch died July 11, 1979, at the age of 76.

DION, ASA, Tufts University, 1928. Dr. Dion was a obstetrician-gynecologist in the Hartford area 1929 to 1975. Dr. Dion was a World War II Army veteran and a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Dion died August 11, 1980, at the age of 78.

GRETSCH, BARBARA, Medical College of Pennsylvania, 1973. Dr. Gretsch was a family practitioner in the Fairfield area since 1975. She served as a first lieutenant in the Women's Army Corps from 1942-1945, and was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Gretsch died August 23, 1980, at the age of 59.

GUALTIERI, MICHAEL V., Tufts University, 1943. Dr. Gualtieri was a family practitioner in the New Haven area since 1943. He was on the staffs of St. Mary's Hospital and Waterbury Hospital, and was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Gualtieri died August 1, 1980, at the age of 61.

MOORE, CLIFFORD D., Queens University, 1928. Dr. Moore was a psychiatrist in the Fairfield area since 1935. Dr. Moore was the first Superintendent of the Fairfield State Hospital in Newtown, CT, and later was Medical Director of Stamford Hall in Stamford, CT. While Superintendent of Fairfield, he was also Associate Clinical Professor of Psychiatry at Yale, and was in private practice in Stamford before his retirement in 1970. Dr. Moore died July 22, 1980, at the age of 77.

MORRISON, JOHN E., University of Maryland, 1946. Dr. Morrison was an internist in the New London area since 1951. During World War II he served as a captain in the U.S. Army. He was clinical director and director of medical and surgical services at the Norwich Hospital for a period of 25 years before retiring in 1974. He was a member of the New London County Medical Association and the Connecticut State Medical Society. Dr. Morrison died July 4, 1980, at the age of 60.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Opportunity to rent professional office, 100 Retreat Avenue, Hartford, CT. 575 sq. ft., close proximity Hartford Hospital. Available mid-September. Inquiries to William B. Laakso, M.D., 549-1900.

To lease modern medical office space. 800 sq. ft. Can be shared with another doctor. Contact: Thomas J. Mirabile, M.D., 100 Retreat Avenue, Hartford, CT.

Aetna Life & Casualty needs an Associate Medical Director in its Employee Health Services Department. Candidate will conduct employee physicals and perform administrative duties. Applicants must be MD's that have or are eligible for a license to practice medicine in CT. Send resume and salary requirements to Bill McKendree, Recruiting Office, Aetna Life and Casualty, 79 Farmington Ave., Hartford, CT 06156. EOE.

Rocky Hill-Independent group seeking physician to share office space on a part-time basis. Ideal as satellite office facility. Adjacent to Century Hills. "Cold Spring Medical Suite," Cold Spring Plaza, Rocky Hill. 529-3211.

EMERGENCY ROOM

Director for Emergency Medical Services must be able to sustain the current high level of departmental morale and quality of care, while preparing for new facilities which are part of a hospital expansion project submitted for state approval in September '80. The Director assumes a leadership role in our community in order to influence and continue programs in pre-hospital treatment, inter-hospital cooperation in trauma and psychiatric services, and development of appropriate relationships with formal education program. Persons interested must have experience with and be committed to both the medical and administrative responsibilities of the service. This position offers an opportunity for personal and professional satisfaction which is supported by co-workers, fellow physicians, and the hospital. The community is family-oriented and located within short distances of cultural centers and the recreational opportunities of Boston, New York, and the upper New England state. Reply to Thomas M. McCaffrey, Executive Vice President or Matthew P. Campione, M.D., Chief of Staff, Meriden-Wallingford Hospital, 181 Cook Avenue, Meriden, CT 06450.

Career Emergency Physician to join full-time group. Emergency Department cares for 34,000 patients yearly, has paramedic program, in seashore community of 53,000 people. Please send CV to Chairman, Department of Emergency Medicine, Milford Hospital, 2047 Bridgeport Avenue, Milford, CT 06460.

FAMILY PRACTICE

Wanted: Part time physician. General Practice, Internist, Family Practice. 8:00 to 12:00 five mornings a week with night and weekend coverage on rotation. Conn. licensed. Masonic Home and Hospital, Wallingford, CT.

FP or Internist: Seeking minority physician to take over large urban practice or recently deceased physician. Minimal capital requirement. Contact: Mrs. Leslie Clark, 120 Sunny Reach Drive, West Hartford, CT 06117. Or call 236-5795.

INTERNAL MEDICINE

Physicians needed part-time for positions starting Fall 1980 for inpatient and outpatient delivery of hospice services with the Connecticut Hospice, Inc. in Branford. Must be board eligible, experience in general medicine preferable. Send letter and CV to Dr. Samual O. Thier, Chairman of Search Committee, 61 Burban Drive, Branford, CT 06405. EOE.

Large Internal Medicine practice for immediate sale in mid Fairfield County, CT. Yale affiliated hospital. Includes office and equipment with x-ray. Send CV to CSMS/IM-FLP.

PHYSICANS WISHING TO LOCATE IN CONNECTICUT

ALLERGY

Available within one month of acceptance: Age 36. Applied for Conn. license. FLEX. AB-cert. Presently in practice. MD: India. Int.: Lakewood Hosp., Ohio. Res.: St. Vincent's Hosp., NY. Fellowship: West Jersey Hosp., NJ. Four years experience in England. Bd. cert. in Allergy and Immunology and ped. Also trained in adult allergy. Solo practice desired in large or med. size community in CT. Contact CSMS/Allergy-AJS.

DERMATOLOGY

Available now. Age 37. Conn. license. Nat'l. bds., elig. MD: St. Univ. of Buffalo. Int.: Mt. Sinai Hosp., NY. Res.: NY Hosp.-Cornell. Looking for part or full time position in private or grp. practice, clinic, hosp., or other setting. Contact CSMS/Derm.-CLS.

July '81. Age 30. Conn. license. Nat'l. bds., cert.-IM; elig.-Derm. MD: SUNY. Int. and res.: (IM) Hartford Hosp. Fellowship: (Derm.) Mt. Sinai Med. Ctr., Miami. Solo, grp. or assoc. type practice in large community in CT. Elliot C. Zweig, M.D., 14310 NE 5 Place, North Miami, FLA 33161.

FAMILY MEDICINE

July '81. Age 37. AB-elig. '81. MD: Autonomous Univ. of Guadalajara. Int. and res.: St. Joseph's Hosp., Stamford, CT. Grp. practice in large or med. community. Paul Berman, M.D., 1425 Bedord St., Apt. 7P, Stamford, CT 06905.

Available now. Age 28. Nat'l. bds., elig. MD: SUNY Brooklyn-Downstate. Int. and res.: Southside-Bayshore Hosp., NY. Solo practice in med. community. Prefers town of 15,000-25,000, Southeast or Northwest CT. Will have physicians' assistant who will be working with him. Michael Karp., M.D., 40-172 West 4th St., Patchogue, NY 11772.

Family Practice and Psychosomatic Medicine: Available immediately. Age 52, AB-elig. MD: Univ. of Minnesota. Int.: Santa Maria, CA. Res.: Santa Barbara, CA. FAA examiner since 1959. Senior examiner for seven insurance companies. Consultant Psychosomatic Med. Adm. Dir./Med. Dir., Churchill Mem. Hosp.; Exec. V.P. and Dir., Solar Lab., Los Angeles. Dir. in charge planning, General Medical Corp. Will consider all types of practice in CT. Bruce R. Little, M.D., 881 Indian Hill Rd., Orange, CT 06477.

Intrapulmonary Benign Cystic Teratoma

MICHAEL SARUK, M.D., HAROLD STERN, M.D., BRUCE S. TRONIC, M.D.,
RONALD D. NEUMANN, M.D. AND VIRGINIA A. LIVOLSI, M.D.

ABSTRACT—A rare example of an intrapulmonary teratoma occurring in the left upper lobe of a 29-year-old woman is reported. This represents the 22nd such case in the world literature and is the first instance in which modern diagnostic radiologic techniques have been used.

Athough mediastinal teratomas comprise a common group of thoracic neoplasms, intrapulmonary teratomas are among the rarest tumors occurring in the chest.[1,2] We present the 22nd reported case of a primary pulmonary benign teratoma with clinical, radiologic and pathologic correlations.

Case Report

This 29-year-old Oriental female presented with several episodes of hemotysis. She had smoked ten cigarettes a day for nine years. Approximately two years before the present admission she developed a chronic non-productive cough. Over the ensuing two years the cough increased and she experienced an uneasy feeling in her chest.

Approximately one year prior to admission she noted the occasional production of small amounts of blood-tinged mucus. The initial episode of hemoptysis was associated with a lower respiratory infection. She experienced two more episodes of hemoptysis in the three months prior to admission; the latter were unassociated with other systemic symptoms.

On admission to the hospital physical examination disclosed slight wheezing especially when she lay on her left side. The remainder of the examination was entirely within normal limits.

Laboratory data including routine blood chemistries, blood count, urinalysis, and liver-spleen scan were within normal limits. A tuberculin skin test was non-reactive.

Chest radiographs disclosed a large irregular mass in the anterior segment of the left upper lobe. No calcification was noted. Hilar enlargement was prominent (Figure 1). A Gallium scan revealed uptake in the area described above.

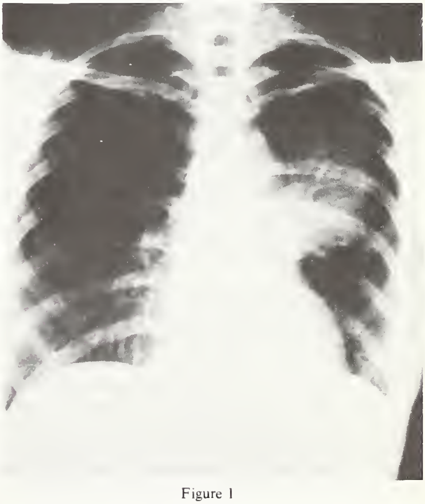

Figure 1
Chest X-ray discloses large left upper lobe lung mass.

MICHAEL SARUK, M.D., Resident in Pathology, Department of Pathology; HAROLD STERN, M.D., Associate Clinical Professor of Surgery, Department of Surgery; BRUCE S. TRONIC, M.D., Resident in Pathology, Department of Pathology; RONALD D. NEUMANN, M.D., Assistant Professor of Nuclear Medicine, Department of Diagnostic Radiology; VIRGINIA A. LIVOLSI, M.D., Associate Professor of Pathology, Department of Pathology; all of the Yale University School of Medicine.

Reprint requests to: Department of Pathology, Yale University School of Medicine, 310 Cedar Street, New Haven, CT 06510 (Dr. LiVolsi).

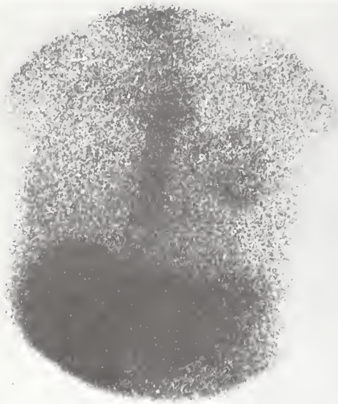

Figure 2
Gallium scan demonstrates uptake of the radioactive nuclide in the abnormal area.

Preoperative liver-spleen and whole body Gallium scans were performed. The left upper lobe lung lesion concentrated Gallium without any abnormal foci noted in the hilum or mediastinum (Figure 2). Isolated images of the lung lesion showed more Gallium concentration in the periphery of the mass. The scan was interpreted as compatible with either inflammatory or neoplastic disease.

The initial clinical impression was that of a low grade tumor or chronic lung abscess.

Bronchoscopic examination disclosed edema of the carina and purulent drainage from the anterior segment of the left upper lobe bronchus. This material continuously welled up from the bronchus despite repeated aspiration. Cytological examination of sputum and bronchial washings failed to demonstrate malignant cells. Bronchial biopsy showed normal histology.

Because of the volume of secretions a Carlens tube was employed for endotracheal intubation. At thoracotomy a large anterior segmental mass adherent to the adjacent mediastinum was noted. Numerous lymph nodes were present in the hilum and mediastinum. Some of these were as large as 3 cm. During the dissection of the medial portion of the tumor adjacent to the mediastinum the mass was entered and a large amount of sebaceous material and hair exuded into the operative field.

Simultaneously the anesthesiologist noted the presence of hair and sebaceous material in the left limb of the Carlens tube. A lobectomy was performed. After removal of the endotracheal tube bronchoscopy was carried out yielding additional sebaceous material from the remaining left lower lobe. The right main bronchus and its divisions were normal.

Her postoperative course was complicated by atelectasis of the left lower lobe requiring bronchoscopy and repeated endotracheal suctionings. She remains well one year later.

Pathology

Gross (Figure 3) The lesion, located in the anterior aspect of the left upper lobe, was completely intrapulmonary and was found to focally extend to within 1/2 cm. of the pleural surface. The mass, which measured 4 x 4 x 4 cm., appeared circumscribed. Centrally a cystic area was noted; within this a yellow-white, pasty, oily material admixed with hairs was found. The outer solid areas were composed predominantly of rubbery, firm, tan, lobulated tissue contiguous with the cyst wall. No calcifications or teeth were recognized. The lung surrounding the mass showed marked consolidation with increased fibrosis. Numerous ectatic bronchi and bronchioles filled with yellow pasty material and hair were seen. The sebaceous-like material was recognized even in the major lobar bronchus.

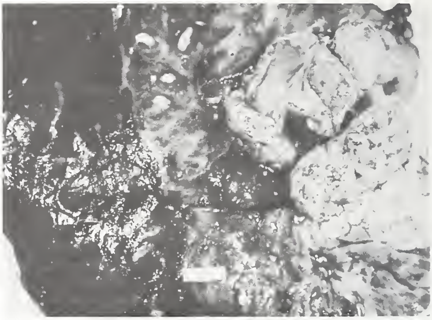

Figure 3
Bisected lobe shows multilobulated friable tumor composed of sebaceous material and solid areas.

Microscopic (Figures 4, 5) Numerous sections of the tumor itself disclosed a totally mature partially cystic teratoma, composed of skin and appendages, cartilage, fat, bronchial glands and respiratory epithelium, colonic mucosa and exocrine pancreas (Figure 4). No neural tissue, bone or teeth were present. No thymic tissue was recognized. Immature or malignant elements were absent.

The lung surrounding the tumor showed areas of chronic organizing pneumonia, interstitial fibrosis, endogenous lipid pneumonia, acute and chronic bronchitis with microabscess formation and extensive bronchiectasis. Keratin debris was identified in some of the small bronchi.

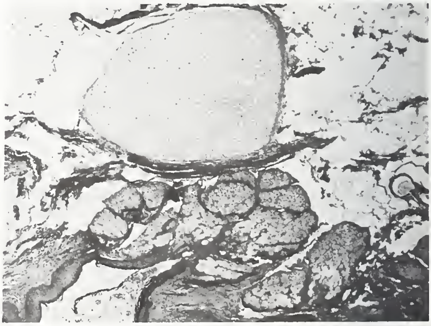

Figure 4
Mature cartilage, fat, skin and sebaceous glands composed large areas of the tumor (Hematoxylin & Eosin, X 125).

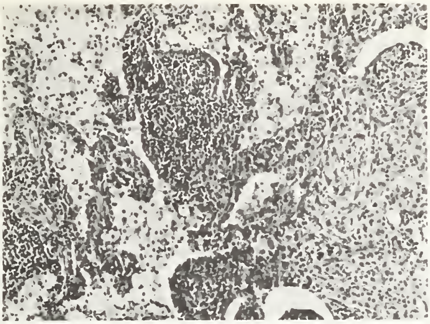

Figure 5
Surrounding the lesion, the lung showed evidence of fibrosis chronic inflammation and lipid pneumonia (Hematoxylin & Eosin, X 200).

In many areas the inflamed bronchi showed erosion and ulceration with exposed exuberant vascular granulation tissue. These areas probably accounted for the hemoptysis.

Discussion

Teratomas are defined as lesions containing three germ layers: endoderm, mesoderm and ectoderm.[3,4] Most teratomas arise in the gonads. The next most frequent site of origin is the anterior mediastinum, usually thymus-associated. Other less common sites include the retroperitoneum, especially the sacrococcygeal area and the pineal region.[3,4] Common to all these extragonadal sites is the predilection for the tumor to arise near the midline of the body.

The pathogenesis and histogenesis of teratomas continue to be debated.[3-5] Linder et al[5] have shown by chromosomal analyses of ovarian teratomas that these lesions were homozygous at loci for which the host was heterozygous. These authors[5] believe that their data are most reasonably explained by assuming that the cell line from which the tumor arose had completed first meiotic division but not the second such division. More careful chromosomal and karyotypic analyses will shed further light on the origin of teratomas. From present knowledge origin from germ cells appears most likely.[3-5]

Intrapulmonary teratomas are extremely rare lesions.[1,2] In 1958 Collier et al[6] reviewed the world's literature and accepted twelve cases of lung teratoma. Ali and Wong[7] included fifteen cases in their report.[8,9] Since then further examples have been added.[1,10,11-14] Some cases reported in the early literature have been inadequately documented or defined and are not included in literature reviews.[1] Our review has shown twenty-one previously documented examples of primary intrapulmonary teratoma.[1,2,6-14]

Our case adheres to the definition of teratoma put forth by Willis[15] as stated above and conforms to the criteria of previously accepted cases.[1,2]

The literature indicates that intrapulmonary teratomas in young to mid adult life are more commonly benign than malignant and show a predilection for the left upper lobe.[1,2] The sex incidence is approximately equal. An intrapulmonary mass lesion, often associated with cough and hemoptysis, is the usual presentation.[1,2] Associated bronchiectasis, pneumonia and abscess are found frequently.[1,2,10]

The origin of intrapulmonary teratomas include thymic rests[15] which develop from a misplaced third pharyngeal pouch. Day and Taylor[1] supported this origin from thymic-associated germ cells. Some examples of intrapulmonary teratoma have been associated with thymus.[1] Although most lung teratomas do not show this association, it may be argued that preexisting thymus has been replaced or destroyed either by the tumor's growth or by the associated inflammatory processes. [That thymic tissue may occur in the lung is evident from the occurrence of intrapulmonary thymomas.[2,17]]

Before accepting any intrapulmonary teratoid tumor as primary, the presence of gonadal immature teratomas must be excluded. In both the ovary and testis, metastases from immature teratoid tumors contain completely mature tissues.[18-20] In the present case gynecologic examination failed to disclose a pelvic mass.

The preoperative evaluation of the lung mass in our case included the use of Gallium scans. This material, phagocytized by leucocytes and histiocytes, localizes inflammatory lesions and zones of necrosis in neoplasms. In our case the "donut" configuration noted on scan corresponded to the lipoid pneumonia and microabscess formation surrounding the tumor. These lesions were produced by bronchial obstruction from both tumor compression and inspissation of tumor products.

^{67}Gallium-citrate is used to study both inflammatory and neoplastic lesions although the exact mechanism of localization is not completely understood. This case represents the first reported pulmonary benign cystic teratoma to be imaged with Gallium. However, it is likely that the greatest Gallium activity was concentrated in the inflammatory response which surrounded the tumor tissue per se.

In conclusion, we present a case of benign intrapulmonary cystic teratoma. The presenting symptoms of cough and intermittent hemoptysis were produced by the associated pneumonitic and bronchitic changes in the surrounding lung. The patient remains well following lobectomy.

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Autosomal Dominant (Adult) Polycystic Kidney Disease in Childhood

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ABSTRACT—Autosomal dominant (adult type) polycystic kidney disease in children has been demonstrated in 27 previous cases. We report a girl who had an enlarged functioning polycystic left kidney at birth and a significant hypertension at age 5½ years. Ultrasonography confirmed bilateral polycystic kidney disease in the patient and showed previously unsuspected cystic disease in the father. The paternal side of the family had a strong history of polycystic kidneys. We emphasize the important role of ultrasonography in the diagnosis and genetic counseling of families with suspected renal cystic disease.

Ultrasonography is valuable in the early diagnosis of polycystic kidney disease.[1,2] The importance of ultrasonography is emphasized by the family reported here in which the presence of autosomal dominant (adult type) polycystic kidney disease (ADPKD) in a child was supported following ultrasonographic demonstration of unsuspected cystic renal disease in the child's father.

Case Report

DM, an asymptomatic 5½-year-old female, presented with a left-sided abdominal mass. The patient was the product of a full term, uncomplicated pregnancy and delivery. Birth weight was 3770 gm.

On newborn examination, a left-sided abdominal mass had been felt. An intravenous urogram at 3 days of age was reported as normal; retrospective study of the radiographs showed enlargement and distortion of the left kidney consistent with ADPKD. The mass was not described on subsequent follow-up physical examination. The patient had no history of other urinary tract problems. Family history revealed two great uncles with known polycystic kidney disease. Hypertension was present in the paternal grandfather but renal cystic disease was never detected (although not specifically studied for this).

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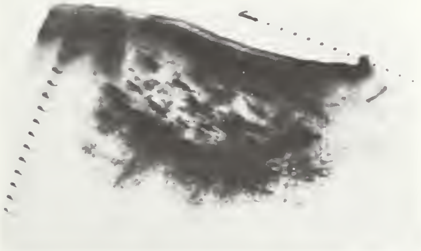
On physical examination, she was 101 cm high and 22 kg in weight. Her blood pressure was 138/98. A firm irregular mass was palpable in the left flank.

Repeated urinalyses showed a specific gravity ranging from 1.009 to 1.018 with a trace of protein. Complete blood count, blood urea and electrolytes were normal; serum creatinine was 0.5 mg/dl and creatinine clearance was 150 cc/min/1.73 M.^{2} Serum renin was 4.7 ng/ml/hr (normal is less than 15 ng/ml/hr).

Ultrasound examination revealed an enlarged left kidney containing multiple cysts of variable sizes (Figure 1A). The right kidney showed several small echo free areas which were interpreted as probably cysts.

An intravenous urogram showed a normal right kidney. The left kidney was enlarged and measured 15.5 cm. It contained multifocal masses altering the renal contour. The nephrogram phase demonstrated multiple round radiolucencies with smooth margins. There was displacement and alterations of the pelvo-infundibular calyceal system as described in ADPKD (Figure 1B).



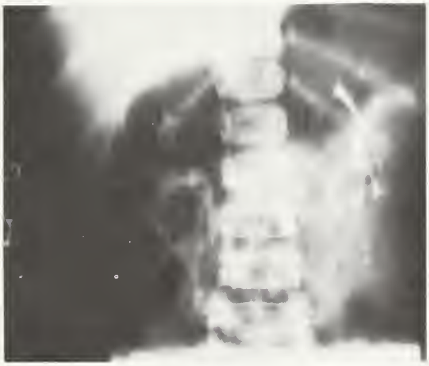


Figure 1B

Tomographic section of the proband's kidney showing a normal right kidney and a large left kidney with alteration and displacement of the collecting system.

A sulphur-colloid liver scan showed the liver to be 14 cm in length. There were multiple small areas of decreased activity suggesting but not definitely demonstrating small defects.

The patient's father (RM) had had an intravenous urogram one year previously because of renal colic. This demonstrated left renal and ureteric calculi but no nephrocalcinosis. No disturbance in the renal architecture was detected then or on retrospective study (Figure 2E). Renal ultrasonography of the father performed after the discovery of his child's disorder showed small cysts in the left kidney (Figure 2A-D) and a normal right kidney. In addition, there was distortion of the central collecting structures probably due to cysts too small to resolve by present methods. These appearances are consistent with ADPKD. The right kidney was normal. Ultrasonography of the mother and sibling of the proband was normal.

The patient was placed on propanolol 10mg twice a day and blood pressure has returned to normal with the most recent blood pressure being 104/64.

Discussion

It is possible that the left kidney of this proband has polycystic involvement at birth. Unilateral ADPKD is not an unusual finding in childhood. In Kaplan's series,[3] four of the eight children had apparent unilateral disease on intravenous urogram.

The occurrence of autosomal dominant (adult) type polycystic disease in children has been reported in 28 cases (Table 1). Very early histologic changes of adult

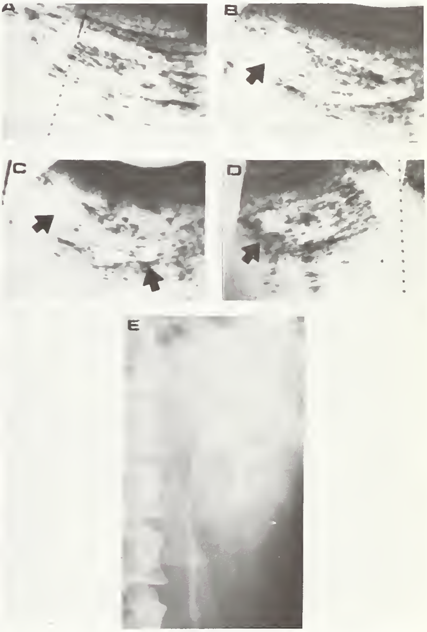


Figure 2

A) Prone sagittal scan of right kidney of father shows normal central renal sinus and normal renal contour.

B-C) Prone sagittal scans of father's left kidney show disorganization of renal sinus echoes with several readily discernible small renal cysts (arrows). The renal contour is slightly irregular.

D) Prone transverse scan of father's left kidney reveals larger cortical cyst arising from lateral aspect lower pole (arrow).

E) Urogram of father's kidneys obtained one year earlier than scans during episodes of urolithiasis; concentration of the dye is seen in the left kidney but there is no calyceal distortion suggestive of cystic disease.

polycystic disease have been diagnosed in a 14-week abortus sibling of a patient with ADPKD.[4] Microscopic cysts have been reported at necropsy in a premature infant who died of sepsis.[5] While the age of onset of symptoms of ADPKD is variable, these factors tend to be fairly consistent within particular families. Our case and a previous report[6] point out that the diagnosis of ADPKD in a parent was made only following diagnosis in their child, emphasizing the importance of careful family history and work-up of parents in order to correctly diagnose the type of cystic disease present. Furthermore, the normal right kidney by urogram in the proband was eventually shown to contain cysts by ultrasound.

This case and other recent reports[1, 2] highlight the great value of ultrasound in the early diagnosis of ADPKD. The correct diagnosis of ADPKD is important for its prognostic implications and for genetic counseling for the family. A careful ultrasonographic work-up of all family members of a patient suspected to have ADPKD should be performed as a screening procedure.

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Table 1

PREVIOUS REPORTS OF AUTOSOMAL DOMINANT ("ADULT TYPE") POLYCYSTIC KIDNEYS IN INFANTS AND CHILDREN

No. of Cases (Reference)	*Age of Diagnosis In Years (Sex)*	*Pathology*	*Radiography*	*Family History*	*Comments*
1 (3)	5 (M)	NA	IVU-polycystic kidneys	positive	
2 (8)	1/12 (M) 4/12 (M)	polycystic (autopsy) polycystic (autopsy)	IVU-polycystic kidneys 2/2	positive positive	endocardial fibroelastosis in both
1 (9)	1/12 (M)	polycystic (gross inspection)	IVU, retrograde-polycystic kidneys	positive	portal hypertension with hepatic fibrosis
1 (10)	6 (F)	NA	IVU-polycystic kidneys	positive	portal hypertension with hepatic fibrosis
4 (4) (+2 fetuses)	1/6 (F) 2 (F) 6 (M) 7/12 (M)	polycystic (autopsy) polycystic (nephrectomy) unilateral polycystic (nephrectomy) polycystic (autopsy)	IVU-polycystic kidneys in 3/3 NA in 1	positive positive negative negative	liver-some fibrosis 2 fetuses had cystic abnormality
1 (11)	1/12 (F)	NA	IVU-polycystic kidneys VCUG-reflux, pyelotubular backflow	positive	hypertension
1 (6)	3/12 (F)	NA	IVU-polycystic kidneys	positive	asymptomatic in mother
2 (5)	1/12 (M) 1/12 (F)	polycystic (autopsy) polycystic (autopsy)		positive positive	
8 (3)	3-9 (5 M) (3 F)	NA	IVU-positive bilateral (4) unilateral (4)	positive in all	6 families with 2 affected siblings in 2 pedigrees
2 (1)	1-6/12 (F) 6 (M)	NA NA	IVU-normal IVU-normal	positive positive	confirmed by ultrasound
4 (2)	9-15 (1 M) (3 F)	NA	NA	positive (1 family)	confirmed or suspected by ultrasound
1 (author's)	5-1/2 (F)	NA	IVU-unilateral polycystic	positive	endocardial fibroelastosis in one uncle
TOTAL 28	MALE 14 FEMALE 14	POLYCYSTIC 9/9	POSITIVE IN 19/21	POSITIVE IN 26/28	

IVU = intravenous urogram NA = not available

Warfarin During Lactation

KENNETH R. DARDICK, M.D.

ABSTRACT—Authoritative sources continue to advise against the use of warfarin during lactation for fear that it will cross the breast milk barrier and anticoagulate the baby as well. A recent article by L'E Orme clearly disproves this advice. This case report again demonstrates that warfarin does not cross the breast milk barrier and does not anticoagulate the baby. Warfarin can be safely administered to a mother who is breast-feeding.

Thrombophlebitis of the deep veins of the legs and pelvis is not uncommon during pregnancy and the puerperium. Intravenous heparin is the initial drug of choice to be followed by administration of warfarin for a period of three to six months.

It is generally accepted that heparin crosses neither the placenta nor the blood-breast milk barrier and is, therefore, safe in either circumstance. There is confusion, however, whether warfarin will cross the blood-breast milk barrier and appear in breast milk. It is common for nursing mothers with phlebitis or pulmonary emboli to be treated with intravenous heparin as the sole form of therapy. If the heparin is stopped after only a short period of time, the patient may develop further clots or emboli. If the heparin is continued for many weeks or months in order to avoid warfarin therapy, an unusually long hospitalization at great expense will result.

Numerous authoritative references on the subject of drugs in nursing mothers still list warfarin as a drug to be avoided during lactation.[1,2,3,4] This is apparently incorrect advice. L'E Orme and others in 1977[5] clearly demonstrated the absence of warfarin from breast milk in nursing mothers taking that drug. This report will describe another demonstration of the safety of warfarin in nursing mothers.

A 35-year-old mother developed massive pulmonary emboli two weeks post-partum. She was begun on heparin anticoagulation intravenously and subsequently switched to warfarin in a daily dosage of 10 mg. Two and a half weeks after beginning the warfarin, the mother's prothrombin time was 22.4 seconds (control 12.1 seconds). She continued to nurse her baby four to five times a day. On the same day that the mother's prothrombin time was 22.4 seconds, the baby's prothrombin time was 10.7 seconds. Warfarin was continued for three months without any evidence of abnormal bleeding in the baby. No further emboli or evidence of phlebitis was noted in the mother during the three months of warfarin therapy.

This is further substantiation of the safety of warfarin in nursing mothers and indicates that there is no anticoagulant effect on babies who nurse from such mothers. Optimal therapy of pulmonary emboli in nursing mothers should include initial treatment with intravenous heparin followed by three to six months of warfarin with regular monitoring of the mother's prothrombin time.

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Percutaneous Drainage of Abdominal Abscesses

Interventional Radiology

CHARLES J. FARROW, M.D. AND STEPHEN STEIN, M.D.

Percutaneous catheter drainage of abdominal and retroperitoneal abscesses has recently been developed as an alternative to traditional surgical drainage procedures. Ultrasound, computerized body tomography and conventional fluoroscopy may be utilized for diagnosis and localization of the infected fluid collection. The case presented below demonstrates the use of percutaneous drainage in the treatment of a postoperative intraabdominal abscess.

Case History

A 70-year-old man was admitted complaining of fever, shaking chills and right upper abdominal pain. Admission SGOT, total and direct bilirubin and alkaline phosphatase were mildly elevated. A double dose oral cholecystogram revealed a nonfunctioning gall bladder and the patient underwent cholecystectomy and exploration of the common bile duct.

The right hepatic artery was lacerated and repaired during the surgery. Postoperative complications included 1) discovery of an impacted distal common duct stone, 2) dislodged T-tube, 3) formation of a subhepatic biloma, and 4) persistent sepsis. The stone was removed via transduodenal papillotomy and the biloma was surgically drained. Because of continuing spiking temperature, abdominal ultrasound was performed revealing a large fluid collection in the posterior left upper abdomen (Figure 1). Ultrasound contolled Chiba needle aspiration and contrast injection localized the abscess to the lesser sac. The stomach was filled with water soluble contrast via NG tube and under fluoroscopic control a large percutaneous drainage catheter was passed between the stomach and colon into the abscess. (Figure 2) 300cc of serosanguineous fluid infected with E. Coli was drained. The patient remained on antibiotics, his temperature returned to normal and the catheter was mobilized and removed prior to discharge.

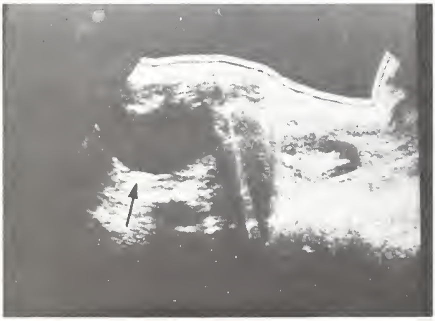

Figure 1
Prone ultrasound of left upper quadrant. Arrow indicates abscess above the left kidney.

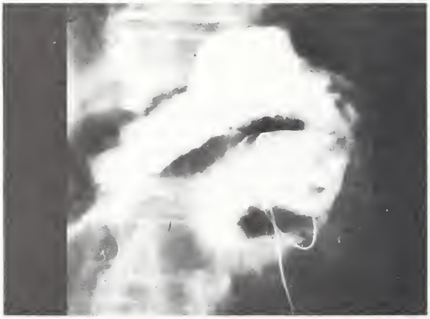

Figure 2
Percutaneously placed catheter coiled in lesser sac abscess. Orally ingested contrast outlines stomach above the abscess.

Discussion

Fluoroscopy and ultrasound have been used for the detection and percutaneous guided aspiration of abdominal abscesses.[1] Recently, computed tomography has been employed as an additional means to precisely localize these lesions and to preserve the integrity of adjacent structures during placement of catheters of appropriate size to effect definitive drainage.[2,3] The catheter is maintained and removed in the same manner as any surgically placed drain. In a recent series[2] twenty-two of twenty-four patients were successfully treated for intra abdominal and retroperitoneal abscess without need for further surgery.

Percutaneous catheter drainage appears to be an effective primary approach to the management of abdominal abscess. Utilizing the anatomical detail provided by ultrasound, computed tomography and fluoroscopy, and employing the same drainage routes as traditional surgical procedures, percutaneous drainage is a safe, cost effective technic that avoids the risks of general anesthesia and exploratory laporatomy.

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An Overview of Obesity: Cause, Concerns, and Control

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Obesity is the number one public health problem in the United States. However the last decade has shown that overnutrition is not simply a matter of overeating, but is a physical condition that involves environment, heredity, emotions, behavior, hormones and perhaps metabolic derangements. Strictly environmental theories concerning overweight have been losing popularity since recent studies have illustrated adopted children favor the body type of their natural not their adoptive parents, and that overfeeding will make them fat only if they have a specific genetic predisposition. Current thinking has recognized the fat cell theory which suggests there are two ways of becoming fat: one by increasing the number of fat cells (hyperplastic obesity) and the other by increasing the size of fat cells (hypertrophic obesity). The creation of new fat cells in a fat-prone individual could occur as early as the last trimester of pregnancy and could continue well into adult life.

There has been a tremendous volume of written material on diet during the past ten years. This is a brief outline of some of the major contributions and their practical relevance in the treatment of obesity.

I. The In Diets (and Out) of The Seventies

From Feast to Famine
From Fat to Fiber

Weight loss diets were big news and big money during the last decade. They ranged from variations of high protein low carbohydrate diets, to low protein high carbohydrate diets. The calorie was temporarily forgotten. Dr. Robert Atkins started the trend with a book called "Dr. Atkins' Diet Revolution." Atkins, a New York City internist, refined the old ketogenic diet known as the "Stillman Diet" or the "drinking man's diet." Foods were assigned various carbohydrate points, and the lower the carbohydrate content of the total diet the more you could eat. This created ketosis in the dieter, which was advantageous for two reasons: it suppressed appetite and it allowed (or so Dr. Atkins said) a large number of calories to be "wasted" by the kidneys in an attempt to buffer the body. Atkins was immediately at odds with medical authorities however, because his diet replaced carbohydrates with fats. He encouraged the use of butter, cream and mayonnaise to increase food palatability. In an era where the linkage between heart disease and fat seemed very clear, Atkins placed himself firmly against the establishment. However, while medical authorities frowned the public ate up Atkins' philosophy, buying over 3,000,000 copies of his book and dining on lobster Newburg.

In Boston about the same time, a totally different approach was being tried. Dr. George Blackburn, at the Center for Nutritional Research, found that obese humans could lose weight rapidly and safely on a diet that replaced only body protein. He and his colleagues used 1 to 1.5 gm. of protein per kg. of body weight in the form of lean meat, fowl and fish as the total daily food intake, plus appropriate vitamins and minerals. He called this diet the Protein-Sparing-Modified-Fast. (PSMF). His patients lost large amounts of weight rapidly and without hunger, under strict medical supervision and with good psychological support systems. At Cleveland Clinic, Dr. Saul Genuth was also using the PSMF principle. The protein used instead of meat or fish was a liquid, milk-based product fortified with carbohydrates, called Casec. Genuth emphasized the protein sparing effect of adding carbohydrates to his regimen. However, both Genuth and Blackburn felt that positive feedback from a large weight loss would help patient compliance on these stringent diets. The idea was new and exciting. During this period Robert Linn, a Philadelphia osteopath, began using a form of liquid protein, called Prolin, in his busy bariatric practice. His success led him to write "The Last Chance Diet" which proclaimed a miraculous new way to lose weight. The liquid protein craze swept the country as a direct result of the book. However, when the statistics were in, over 50 female patients who had been ingesting liquid protein as their total caloric intake for periods of 8 to 16 weeks were dead. The causes of death were intractable arrhythmias, characterized by ultrastructural changes in the myocardium. Suggested reasons for this bizarre complication included possible deficiencies in essential metals, potassium, magnesium

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and copper or that liquid protein, made from collagen, was an inferior protein that could not be utilized by the cardiac muscle. The PSMF program instantly lost its popularity.

By this time people were tired of "the dangerous diets." They wanted to live longer, not die sooner. It was in this ripe climate that Nathan Pritiken, a non-doctor, emerged with his Longevity Center in California. His diet philosophy represented a total change. The Pritiken Diet was not a weight loss diet, per se—although there was a weight loss version of it. However, it advocated no fat, no cholesterol, no salt, no sugar, and no additives; and followers often experienced dramatic weight loss. The mainstay of the diet was natural grains, dried legumes, fresh fruits, vegetables, and very small amounts of lean poultry or fish. Pritiken claimed dramatic reductions in atherosclerosis, hypertension and diabetes for those who followed his plan exactly. Experts in nutrition and cardiovascular disease felt, however, that perhaps the same results, e.g., lower incidence of coronary artery disease, arteriosclerosis, bowel problems, high blood pressure and diabetes, could be achieved by a less spartan and therefore more realistic regimen than Pritiken's.

No diet survey of the '70's would be complete without mentioning the Scarsdale Diet. It was merely a low fat version of the high-protein, low-carbohydrate diet but it became extremely popular. This was probably because it spelled out exact meals for two weeks and promised "medically approved" fast weight loss.

II. The Downfall of the Uppers

The Demise of the Diet Pill and The Rise of the Behavoral Therapies

Amphetamines, as such, were developed in the mid-1930's to treat narcolepsy, a rare sleep disorder. After introduction into medical practice, they were used for a wide variety of conditions that included depression, fatigue, and ultimately appetite control. In the '40's and '50's they were dispensed freely, often without limits or follow-up. The normal amphetamine dose for dieting was between 2.5 to 15 mg. per day and physicians felt at this dose that these drugs were useful, safe and effective.

The medical community did not anticipate or understand their abuse potential. Amphetamines became a "drug on demand." In 1978 the diet pill investigation chaired by the late Senator Philip Hart, focused on deaths associated with the use of appetite-supressant drugs in combination with other drugs for the treatment of obesity. This investigation led the Federal Government to limit the use of amphetamines and dextroamphetamines to the treatment of narcolepsy and hyperkinetic behavior disorders in children, and only recommended them as a short term adjunct therapy to weight-loss dieting, for patients refractory to other forms of treatment.

Diet pills decrease the appetite of the individual who must restrict his or her intake to lose weight. This theoretically makes dieting easier. The problem was their indiscriminate use as a total diet therapy. Because of their uncertain status, all diet pills have now become part of a Controlled Substance Act, where they are placed on schedules from I to V. When drugs are scheduled, they are classed for safety, current accepted medical use, and abuse potential. The amphetamines are class II.

In recent years a number of drugs have been manufactured and marketed to replace amphetamines as appetite suppressants. They are generally less potent, and their abuse potential has not yet been established. They are classed III and IV and include the now commonly used drugs benzphetamine (Didrex), chlorphenteramine (Pre-Sate), chlortermine (Voranil), dietylproprion (Tenuate, Tepanil), fenfluramine (Pondimin), mazindol (Sanorex), phendimetrazine (Plegine), and phentermine (Ionamine).

Diet pills would be acceptable if one could find a pill that would be effective without toxicity, development of tolerance and adverse metabolic effects. Then its use should be combined with nutritional training, behavior modification, and psychological support systems. As of this writing, "the ideal pill" has not appeared and as with any therapeutic modality the physician should be allowed to judge the risk-benefit ratio of the available drugs.

As the popularity of diet pills declined it became apparent a non-chemical adjunct to diet therapy was needed. Over ten years have elapsed since Richard Stuart published the results of the use of behavior modification techniques in the treatment of dieting. Although behavioral principles were not new, and were being used in the field of education, they were innovative in the field of dieting. After all, eating practices are learned patterns of behavior, therefore obese people must have learned patterns that are inconsistent with being thin. They must go through what the behaviorists call "cognitive restructuring" or, in plain language, "change." They do this by careful record-keeping of past (unsatisfactory) eating-behavior and present (proper) eating-behavior.

Reward is an impetus for changing behavior. In 1972, Stuart's book, "Slim Chance In a Fat World," outlined guidelines for getting a firm control on eating environment. They included choosing where and when to eat, size of portions, speed of eating, and increasing knowledge of nutrition.

If behavior can be altered by repeated conscious suggestions, then it should be that much easier to change both attitude and behavior by the use of hypnosis. Hypnosis is a state of "altered suggestibility" and its use in changing habit-patterns has become impressive. Dr. Herbert Spiegel of Columbia College of Physicians and Surgeons has used single hypnotic suggestions in treating stuttering, smoking, nail-biting, and assorted phobias. Classic psychiatry has backed away from this treatment because it was believed that the habit or fear is an expression of an underlying symptom, and if that habit is taken away, the symptom could manifest itself in another way. This has not appeared to be the case. Unfortunately, however, the habit that appears to be the most resistant to hypnosis is overeating. Most obese patients can enter the "light trance" state, and Spiegel contends this is good enough for change. However, most hypnotists agree that, when used, hypnosis should emphasize positive suggestions rather than the old aversion techniques that popularized the late 1960's (e.g., you will see rats when you look at sweets). It is also presently felt that it is valuable to teach the patient autohypnosis so he can reinforce the positive suggestions himself.

III. The Surgical Treatment of Obesity

Dramatic Measures for Dramatic Problems

"Morbid obesity" is defined as obesity that is so severe that it interferes with work, play, social activity, and personal hygiene, or where body weight exceeds more than twice the estimated ideal weight or greater than 100 pounds. These people have tried every conceivable weight-loss plan and have emerged heavier and more frustrated than ever. It is because of this that surgical control for "morbid obesity" has become more common. Original surgery for fat involved lipectomies. The surgeon would remove chunks of unsightly adipose tissue, leaving the "victims" with massive electrolyte depletion, infections, and ultimately disfiguring scars. Current surgical procedure for obesity, however, manipulates the absorption of food. On April 1954, the first short-bowel syndrome was produced for weight loss. Since then the use of intestinal by-pass has employed end to end anastomosis of jejunum and terminal ileum or colon. Complications of the operation have included fluid and electrolyte imbalance, fatty liver, liver failure, renal failure, enteritis, malnutrition, intolerant anal and perineal irritation and, most recently, bone disease. Less dangerous but annoying is the continual diarrhea and foul-smelling gas that required many of the patients to carry spray deodorants. The side effects of these procedures were so numerous that the operation has been virtually discontinued. A majority of people treated this way had to have normal bowel function restored.

In 1966, Edward E. Mason, M.D., Professor of Surgery at the University of Iowa Hospital, instituted the gastric bypass now replaced by the gastroplasty as a means of limiting food intake in the morbidly obese. The stomach is partitioned so the upper functioning portion has a 50 ml. volume. The patients can eat only small amounts, but the amounts they do eat go through the normal digestive process. The operation has a low mortality rate (less than 1%) and this is usually from infection or pulmonary embolism. If patients eat too much they vomit. Reports indicate 85% of the patients who have had this operation reach their ideal weight. However, many still have to go on a calorie restricted program to lose weight, but interestingly enough, they report "normal" appetites, less pre-occupation with food and less craving.

Those of us who currently treat morbid obesity understand the limitations of traditional weight loss therapy and are beginning to see the gastric bypass (in qualified hands), and accompanied by behavioral training and psychological support as a promising addition to the treatment of severe obesity.

IV. Body Movement Becomes More Important in Total Fitness and Weight Loss

"One major contributing cause for obesity could be the decreased physical activity of the T.V. age."

There are four basic types of exercise that perform different functions for the body. They include exercises that increase cardiovascular efficiency, muscular strength, muscular endurance, and flexibility and elasticity of a muscle group. During the past ten years we have become more concerned with the first type or the aerobic exercises. These not only tend to increase physical fitness but may also enhance weight loss. The 1970's became the decade of the jogger. James Fix's first book on running sold more than 1,000,000 hard cover copies. All forms of exercise that placed substantial stress on the body became extremely popular. They include (in addition to jogging) brisk walking, running, cross country skiing, swimming, and bike riding.

Overweights as a group don't seem to be naturally energetic. They argue that exercise burns so few calories that it's not worth it. They must be made to realize that movement encourages increased oxygen consumption and raises basal metabolic rate. It also decreases the appetite by elevating body temperature and increasing breakdown products from muscle. Exercise probably protects against muscle loss and encourages fat-burning. They must be taught to move just as they were taught to eat. The new designation for calories burned per minute of activity will give them a more realistic idea of caloric expenditures.

Commercial exercise centers have done a great deal to encourage the average American to expend calories. They started as places for obese women to get their fat passively pounded away, and have emerged as complete and self-sufficient centers that encourage aerobics, calisthenics and good nutrition.

V. Big Business Gains a Stronghold in Dieting

> "Private industry may well prove to be the most appropriate vehicle to effectively organize weight control as a health priority. This era might see the management of major health problems passing out of medical hands and into those of private industry."

During the early '60's when Weight Watchers was organized by an enterprising housewife who had been successful in losing weight herself, no one imagined how successful it would become. Up to that point, weight loss was supervised by the often disgruntled and disenchanted physician. The overweight population had few choices. The Weight Watchers formula of regular weigh-ins, group interaction and persuasive speakers offered a much needed alternative for the dieter. Last year Weight Watchers was purchased by the Heinz Company for $71,000,000. It is now bolstered by a staff of physicians (including Richard Stuart of Behavior Modification fame), nutritionists and public relations people. They run a nutritionally sound program which meets all USDA standards. The same basic diet is given to everyone, with variations for men, women and youth. They have also developed a "plateau diet" for those who stop losing weight for no apparent reason. The basic weight-loss diet for women is approximately 1200 calories, and the plateau-diet about 1000 calories. However, the emphasis is on portion control and use of the word "diet" is frowned upon because it implies calories. Although Weight Watchers has stated "no change" after their purchase by Heinz, there has been a substantial increase of printed handouts and advertising copy.

Catering to people who want one-to-one counseling, another highly successful weight-loss program called Diet Center has emerged. This started as a commercial venture in 1970. In the eight years since its inception, it has expanded to 600 centers throughout the U.S. and Canada. The program emphasizes quick weight-loss, and keeping weight off after losing it. The centers are usually run by nutritionists, LPNs or RNs who provide daily support, education, and encouragement to the dieter at a fee of about $25.00 per week. Some centers have prepayment contracts which decrease the number of "drop outs." The diet is low-calorie (far below 1000 calories) but balanced. A daily supplement is also given.

Every day there are new privately owned diet franchises emerging. Along with these, and the non-commercial Overeaters Anonymous and Diet Workshop, overweights now have viable choices. In addition private hospitals and medical schools have been providing behavior modification programs for the general public.

VI. The Government Enters the Diet Field

> "Six of the ten killer diseases are related to diet. These include heart disease, obesity, diabetes, hypertension, cancer, and cardiovascular disease."

The above statement prompted the government to take a long look at what the people in the United States are eating. As a result, in 1978 "Dietary Goals for the U.S." was released by the Senate Nutrition Subcommittee, chaired by George McGovern. It was the first attempt by a government agency to suggest a national policy in nutrition. The agency stated to avoid overweight; reduce consumption of refined sugar, increase consumption of complex carbohydrates, reduce consumption of saturated fat, reduce cholesterol consumption, and limit sodium intake. These suggestions were taken a step further by the Department of Agriculture, and Health, Education and Welfare. These departments are expected to play a regulatory role in America's diet, and have already made changes in school-lunch programs, influenced new food-labeling, and are trying to change meat-grading. They also emphasize moderation; eat a variety of food; if you drink alcohol, do so in moderation; maintain ideal weight; avoid too much fat and sodium; and eat more foods with adequate starch and fiber.

It would be hard to argue the good intent of all the goals, but there are those that feel after years of concerning themselves primarily with food additives and vitamins, the federal agencies have come on a bit too strong, and as one critic put it, "We can't assume that all Americans are prone to diet-related diseases."

In spite of seeming progress, certain inherent problems still exist in any diet treatment plan. Patient compliance, good follow-up records, and recidivism haunt all formal weight-loss programs. Some feel the emergence of a therapeutic team consisting of a physician, psychologist or counselor, and nutritionist would be of the greatest benefit to the overweight patient. Unfortunately, a program like this would be extremely expensive unless there is academic or government subsidy.

Today's physician states that the medical treatment of obesity is not "cost effective." With this excuse, he has relegated the care of the overweight to the nutritionist, psychologist or the diet group. It appears that many of these resources are not cost effective either as the price to treat obesity on all levels continues to escalate.

We are ultimately left, however, with a situation where the people with the most severe overweight problems (the lower socio-economic groups) have the least availability of treatment. This is enhanced by the fact that insurers refuse to regard uncomplicated obesity a reimbursable condition.

If physicians would look at obesity as a metabolic disease like diabetes and not only as an irritating psychosocial problem, they could be in a unique position to offer service. They could supply the medical expertise, supportive therapy, behavior modification, and nutritional information and be cost effective!

It will be interesting to see what happens during the 1980's in the whole area of human overnutrition. Perhaps someone will develop the magic pill, one that will convert food into energy or block the absorption of carbohydrates, and then our behavioral advances will become obsolete and obesity will be a disease of the past. Until that time it is important not to shut out any option that might offer help to the oppressed dieter.

The Role of Dietary Management in Hypertension

RAY W. GIFFORD, JR., M.D.

There are two dietary approaches to the treatment of hypertension: sodium restriction and control of obesity. There is reason to believe they may be effective, either alone in mild hypertension or combined with pharmacotherapy in patients with moderate or severe hypertension.

Sodium Restriction

Epidemiologic and Experimental Observations

Few physicians would question that sodium can aggravate hypertension in some patients. In addition to the clinical experience of the practitioner, there is epidemiologic and experimental evidence to support this thesis.

Hypertension is virtually absent among people of primitive cultures who consume little salt.[1] Moreover, blood pressure does not rise with age in these population groups, whereas it does rise with age in acculturated societies with relatively high salt consumption. In northern Japan where per capita consumption of salt is at least 25 gm daily, the prevalence of hypertension is said to be 40 percent, the highest in the world.[2] Among the Yanomamo Indians in Brazil, who consume about 1 mEq of sodium daily (about 60 mg salt), there is no hypertension.[3]

Sodium Equivalents
One gm salt (NaCl) = 400 mg sodium = 17 mEq sodium
One gm sodium = 2.5 gm salt = 42 mEq sodium

As convincing as these reports may seem regarding the relationship between dietary sodium and hypertension, there are confounding influences such as body weight, potassium intake, the high prevalence of debilitating diseases such as malaria and parasitic infestations, and the effect of "stress" in these populations which make it difficult to determine the exact role of sodium.

A high potassium intake has been shown to partially protect salt-sensitive rats from the hypertension effects of a high salt diet.[4]

Several groups of investigators have failed to demonstrate a relationship between dietary sodium intake (usually estimated from the habit of adding or not adding salt to food or from urinary sodium excretion) and blood pressure within population groups,[5-8] although Morgan et al[9] have shown such a relationship. It is postulated that in Westernized societies sodium consumption is so high that even those who do not add salt to their food have enough sodium in their diets to foster the development of hypertension in genetically susceptible individuals.

Swaye, Berrettoni, and I[10] could find no difference in salt consumption estimated from salt shaker preference between normotensive and hypertensive subjects. But within the hypertension population, those who used salt before tasting tended to have more severe hypertension and more hypertensive complications.

While Kirkendall et al[11] failed to induce hypertension by administering 24 gm of salt daily to normotensive volunteers, Kawasaki et al[12] identified a group of hypertensives whose weight and blood pressure increased with salt loading. Perhaps equally important was the observation that some hypertensive patients had little or no rise of blood pressure or body weight with salt loading. They designated the former group as "salt sensitive" and the latter as "non-salt sensitive."

Schechter et al[13] reported that hypertensive patients showed a greater preference for a saline solution as drinking water than did normotensive controls when both were placed on a 9 mEq sodium diet and given free access to both distilled water and a .15 M solution of sodium chloride.

Years ago Dahl[14] selectively inbred strains of rats that were either "salt sensitive" or "salt resistant." Rats in the former group were easily made hypertensive by increasing salt in their diets, whereas rats in the

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latter group remained normotensive in spite of increased salt rations. Tobian et al[15] have been able to prevent the onset of hypertension in the salt-sensitive strain of Dahl rats by administering a diuretic.

The mechanism by which sodium augments hypertension is not conclusively defined. There are at least three possibilities:

a) Volume. If salt is retained, fluid will be retained with it thus increasing extracellular fluid volume, which by increasing venous return and cardiac output can elevate blood pressure. Experimental data from Guyton's laboratory[16] and from Tobian's laboratory[17] suggest that blood pressure rises in response to an increase in extracellular volume leading to a pressure natriuresis that returns extracellular fluid volume to normal but at the expense of increased blood pressure to maintain homeostasis. This would explain why (1) most hypertensive patients do not have elevated blood or extracellular fluid volume and (2) reducing blood pressure with other than natriuretic agents frequently results in fluid retention.

b) Vascular reactivity. Friedman et al[18] have demonstrated that a decrease in the ratio of extracellular to intracellular sodium leads to increased reactivity of the cell to stimulation. It is conceivable that sodium-loading leads to migration of enough sodium ions into arteriolar smooth muscle cells to decrease the Na_e/Na_i ratio and thereby make the arteriole more sensitive to sympathetic stimuli. This could lead to increased total peripheral resistance and this has been shown to occur in forearm flow studies in hypertensive patients after salt loading.[19] An increased sodium content has been demonstrated in the red and white blood cells of some hypertensive patients.[20, 21]

c) Edema of the vascular wall. Tobian has shown that the walls of small arteries and arterioles in hypertensive animals[22] have a higher sodium and probably a higher water content than those of normotensive controls. This leads to a thickening of the vascular wall at the expense of the lumen and hence resistance to flow increases and if enough of the vessels are affected, blood pressure would rise.

It is entirely possible that all three mechanisms participate to varying degrees with or without other as yet unidentified mechanisms.

Whatever the mechanism, experimental and clinical observations would support the thesis that heredity plays a major role in the sensitivity of blood pressure to sodium. Perhaps it is a defect in the renal handling of sodium and/or the flux of sodium and potassium in and out of cells and vascular walls.[21] This implies that some individuals, like Dahl's rats, are resistant to the hypertensive effect of sodium and others are quite sensitive. There must be all gradations between, making dietary sodium restriction more important for some than for others.

Freis,[23] in his excellent review article, perhaps overstates the case by concluding that hypertension would virtually disappear as a major public health problem if the American diet contained less than 2 gm of salt daily.

Clinical Trials

In spite of the evidence cited for the relationship between dietary sodium intake and hypertension surprisingly few attempts have been made to confirm the effect of low sodium diets with controlled clinical trials in hypertension patients. Ambard and Beaujard[24] are generally given credit for first suggesting that hypertension might be alleviated by dietary sodium restriction. Later, Allen[25] also suggested treating hypertension with low sodium diets.

Kempner[26] popularized his rice diet in the 1940s and showed that it could reverse the malignant phase of hypertension. Dole et al[27] demonstrated that the benefits of Kempner's diet could be attributed to its low sodium content (about 160 mg).

In 1973 Parijs et al[28] reported that moderate dietary sodium restriction in 17 patients resulted in an average 24-hour sodium excretion of 92 mEq (control was 191 mEq/24 hours) and a reduction in supine blood pressure taken at home in the morning from 148/98 to 138/92 mm Hg. An oral diuretic given to the same patients reduced the supine blood pressure from 147/98 to 131/88 mm Hg; the low sodium diet plus diuretic reduced the blood pressure to 126/86 mm Hg. The hypotensive effect of the low sodium diet was of borderline statistical significance ($p < .05$), whereas the reduction in blood pressure produced by the diuretic or diuretic plus diet was highly significant ($p < .0025$).

Prior to this report it was generally believed that to be effective in reducing blood pressure dietary sodium had to be reduced to less than 1.0 gm daily (approximately 2.5 gm of salt) which is an unrealistic restriction for most patients. This study was also the first to demonstrate the additive effect of an oral diuretic and a low sodium diet.

In 1975 Carney et al[29] studied 12 patients, 11 of whom were on non-diuretic antihypertensive agents. A low sodium diet caused a further reduction in standing blood pressure from 163/106 to 148/99 mm Hg, whereas a thiazide diuretic reduced the blood pressure from 163/106 to 140/94; the combination of the diuretic and low salt diet resulted in a blood pressure of 133/93 mm Hg (not significantly lower than the thiazide alone). The prescribed diet contained 70 mEq of sodium daily, but only three patients achieved this as estimated from 24-hour urinary sodium excretion; the others excreted between 70 and 120 mEq of sodium daily.

More recently Morgan et al[30] compared a low sodium diet, chlorothiazide (plus methyldopa in some cases), and propranolol plus a diuretic in borderline hypertensive patients in separate groups of 31 each. The hypotensive effect of each regimen was about the same on diastolic pressure in both supine and standing positions. The propranolol-thiazide regimen had the greatest effect on systolic blood pressure, and the diet had the least effect although it did produce a 10 mm Hg decrement, both systolic and diastolic in the standing position. The diastolic blood pressure was reduced to less than 90 mm Hg for 32 percent of the patients on low sodium diet, for 52 percent of those patients on chlorothiazide, and for 42 percent of those on propranolol-thiazide.

Although the goal of dietary sodium restriction was 70-100 mEq of sodium daily, the average 24-hour sodium excretion of patients on the diet was 157 mEq.

Hunt and Margie[31] have reported their experience in managing more than 3000 hypertensive patients for at least five years at the Mayo Clinic. Initial management was with diet alone. When diastolic blood pressure was 130 mm Hg or more, dietary sodium was reduced to 20 mEq daily; for patients with less severe hypertension the objective was to reduce dietary sodium to 40-60 mEq daily. For all patients an attempt was made to control calories to achieve and maintain ideal body weight. Almost two thirds of all patients who were able to maintain a 24-hour urinary sodium of less than 75 mEq were normotensive without medication. When the pretreatment diastolic blood pressure was 90-104 mm Hg, 85 percent were normotensive at this level of sodium excretion. Of the patients whose urinary sodium was higher than this, only 12 percent were normotensive on diet alone.

When diastolic blood pressure was not below 95 mm Hg at the end of three months on nutritional therapy (one month for patients whose diastolic blood pressure was > 130 mm Hg), antihypertensive drugs, usually a diuretic, were added to the regimen. For those patients who maintained their 24-hour urinary sodium at less than 75 mEq, 98 percent were rendered normotensive with a diuretic alone if the initial diastolic blood pressure was 90-104 mm Hg and 75 percent were rendered normotensive by the diuretic if the initial diastolic blood pressure was 115 mm Hg or more.

Ram and Kaplan[32] have shown that moderate dietary sodium restriction to 64 mEq/day minimizes potassium loss in the urine in patients who were receiving an oral diuretic. However, more rigid dietary sodium restriction to 17 mEq/day[33] or 50 mEq/day[34] aggravated diuretic-induced kaliuresis, possibly because of overstimulation of the renin-angiotensin-aldosterone system.

Practical Considerations

There is no doubt that dietary sodium restriction is beneficial in the management of hypertension. However, achieving and maintaining dietary sodium intake below 100 mEq daily is difficult at best, and practically impossible for patients who must eat many of their meals out of the home. The simple admonition to avoid using the salt shaker is inadequate because only 30 percent of the daily sodium intake is derived from adding salt in the preparation of food or at the table. Most canned foods, commercially prepared meals (e.g. "TV Dinners"), and some other frozen foods contain so much sodium that they must be excluded or sharply curtailed by patients who have to restrict dietary sodium to less than 100 mEq daily. In addition to avoiding the commercially prepared foods already mentioned, persons wishing to achieve a low sodium diet intake must also limit their consumption of grain and cereal products, meat, fish, poultry, and dairy products. Table 1 lists the sodium content of some common foods; Table 2 lists the sodium content of commercially prepared foods; and Table 3 lists some foods that contain so much sodium that they must be eliminated or sharply curtailed.

Softened water and some water supplies are high enough in sodium content that this must be considered for patients who must restrict their daily intake of sodium to less than 1 gm daily.

Table 1
SODIUM CONTENT OF SOME COMMON FOODS

Food	*Sodium Content (mg)*
Fresh unsalted beef, lamb, pork, veal, poultry, fish	25 per ounce
Egg	65 per egg
Bread	150 per slice
Cake, pie, cobbler	400 per serving
Cereals, (corn flakes, rice krispies, wheaties)	200 per ½ cup
Milk	120 per cup
Butter, margarine, French dressing, thousand island dressing, blue cheese dressing	50 per teaspoonful

Nutritive Values of American Foods Agri. Handbook #456. U.S. Dept. of Agriculture.

Table 2
SODIUM CONTENT OF SOME PROCESSED FOODS

Food	*Sodium Content (mg)*
Tomato catsup	156 per tbsp.
Beef frankfurter	627 per frankfurter
Bologna	369 per 1 oz. slice
Tomato Juice	486 per cup
Cinnamon roll (Pillsbury)	330 per roll
Chicken noodle soup	1223 per 10 oz.
Frozen turkey dinner (Swanson)	1060 per dinner
Large dill pickle	1928 per pickle
Canned green beans	564 per cup

Nutritive Values of American Foods Agri. Handbook #456. U.S. Dept. of Agriculture.

Table 3
EXAMPLE OF FOODS WHICH MUST BE AVOIDED
OR MARKEDLY CURTAILED ON A 2 GM SODIUM DIET

- Bacon, Canadian bacon
- Ham, salt pork, sausage
- Dried beef
- Luncheon meats
- Frankfurters
- Kosher meats and fish
- All canned meats and fish
- Smoked or cured meats
- Anchovies
- Shell fish
- Most cheeses
- Baking, pancake, waffle mixes
- Instant hot cereals
- Potato chips, corn chips, pretzels
- Pickles, olives
- Sauerkraut
- Canned and frozen soups, soup mixes
- Gravy mixes
- Buttermilk, evaporated milk
- Milkshakes, eggnog
- Vegetable juices
- Catsup, mustard, chili sauce, horseradish, soy sauce, steak sauce
- Seasoned salts, kelp, "lite" salt
- Accent, meat tenderizers, MSG, baking soda and baking powder

The intricacies of dietary sodium counseling are so great that unless the physician is unusually knowledgeable in this area and has the time to instruct the patient and his family and answer their questions, it is preferable to seek the services of a qualified nutritionist. Simply handing the patient a printed sheet of instructions is of little or no value.

Adherence to sodium-restricted diets can be easily monitored by measuring the sodium content in 24-hour urine specimens. The physician who does this will almost certainly be dismayed.

Weight Control

Epidemiologic Observations

Data from the Framingham Study showed a clear-cut relationship between body weight and the prevalence and incidence of hypertension.[35] Forty-seven percent of men and 46 percent of women, age 50-59 years, who were more than 14 percent over their standard weights calculated from the Framingham cohort were hypertensive (> 160/95 mm Hg) at the initial examination. In the same group, only 13 percent of men and 18 percent women who were under 85 percent of Framingham standard weight were hypertensive.

The risk of developing hypertension within eight years was more than three times as great for Framingham residents who were 20 percent or more above their standard weights at their initial examinations than for those who were at or below standard weight.[35]

The risk of developing some manifestations of hypertensive heart disease (cardiac enlargement or ECG changes of LVH) was more than ten times as great for those who were at least 20 percent above their standard Framingham weights compared to those whose weights at the initial examination were less than this.

Moreover, those who gained more than 29 pounds since age 25 had almost four times the risk of developing hypertension in 11 years as did those who lost weight in the same period.

Perhaps the most surprising finding of all was that hypertension also predisposed to obesity. Men and women who were hypertensive but lean at the first examination, had twice the risk of being obese within 10 years than those who were normotensive initially.[35]

In 1969 Chiang et al[36] reviewed the world literature on the relationship between overweight and hypertension. The evidence is overwhelming that hypertension is more common among the obese than among the nonobese and, conversely, that a large proportion of hypertensive persons are overweight. There is a relationship between blood pressure and relative body weight,[35] and most population studies tend to show a rise of blood pressure with increase of body weight or adiposity.[36] Populations that show the least rise of blood pressure with age are those with lower average weight.[37]

In a Nationwide Community Hypertension Evaluation Clinic (CHEC) program in which more than one million people were screened for hypertension, the group classifying itself as overweight had prevalence rates of hypertension of 50 to 300 percent higher than other screenees.[38] Frequency of hypertension (diastolic blood pressure > 95 mm Hg) in overweight (by screenee's own estimate) persons aged 20-39 years was double that of persons of normal weight and triple that of underweight persons. Among those aged 40-64 years, the overweight group had a 50 percent higher hypertension prevalence rate than the normal weight group and 100 percent higher than the underweight group. The higher the diastolic blood pressure, the higher the relative frequency of hypertension in overweight compared with normal weight persons.[38]

The relationship between body weight and blood pressure has been confounded by arm girth, which is known to artifically increase indirect blood pressure measurements when standard cuffs are used on obese arms, and by concomitant intake of sodium.

There is agreement by those who have examined the problem that arm girth is not a major factor in the relationship between blood pressure and body weight.[35, 36, 39]

The relationship between body weight, sodium intake, and blood pressure is not as easy to study as that between body weight, arm girth, and blood pressure. It seems reasonable that sodium consumption should vary directly with caloric intake. Moreover in those populations whose blood pressure is low and rises minimally if at all with age,[37] not only does body weight remain low throughout life but so does sodium intake.

Page[40] cites observations in several population groups where there seems to be a divergence between body weight and sodium intake and concluded that both variables influence blood pressure directly and independently, but of the two, sodium has greater power as a determinant of individual blood pressure.

In Evans County, Georgia, Johnson et al[41] measured the blood pressures of 436 young adults, age 15 to 29 years, on two occasions seven years apart. Weight was directly associated with both initial blood pressure and the prediction of subsequent blood pressure.

The mechanism by which an increase in body weight raises blood pressure is even more poorly understood than the mechanism by which excessive sodium intake raises blood pressure. The observation that not only does obesity predispose to hypertension, but hypertension predisposes to obesity suggests a very complex relationship between the two.[35] Page has stated that it is body mass, not just adiposity, that correlates with blood pressure for the correlation is just as strong in lean and muscular people as in the obese.[40] Page also believes that the effect of body mass is not heavily dependent on genetic susceptibility whereas the effect of sodium is.[40]

Clinical Trials

There have been even fewer controlled clinical trials investigating the effect of weight reduction on blood pressure in hypertensives than there have been with dietary sodium restriction.

Fletcher[39] reported an average reduction of 30 mm Hg systolic and 17 mm Hg diastolic in 38 obese hypertensive women who lost an average of 33 pounds compared to a slight rise in blood pressure for 21 obese women who lost an average of four pounds. No attempt was made to maintain sodium intake at prediet levels for these patients.

Comparing dietary sodium restriction with weight reduction diets in different groups of obese hypertensive patients, Dahl et al[42] concluded that the former was more effective.

Hunt and Margie's nutritional approach to the treatment of hypertension included both sodium and weight control, but no attempt was made to distinguish between the relative effect of the two.[31]

By maintaining sodium intake at relatively high levels while obese hypertensive patients were put on weight reduction diets, Reisin et al[43] were able to normalize blood pressure without antihypertensive drugs for 18 of 24 patients who lost an average of 9 kg. Additionally, weight reduction normalized blood pressure for 35 of 57 patients who were also on drug regimens that had been ineffective before dietary therapy was started. This group lost an average of 10 kg. Serving as a control group were 26 patients who were on drug regimens that were ineffective. They lost no weight and none became normotensive. They concluded that marked reductions of blood pressure could be accomplished by weight control without sodium control.

Practical Considerations

Weight control is as difficult to achieve, if not more so, than dietary sodium restriction, thus making this otherwise attractive therapeutic approach impractical for many patients who could benefit from it. Most "fast foods," convenience foods, and commercially prepared foods are as laden with calories as they are with salt, consequently the patient who conscientiously wishes to lose weight has difficulty if he/she has no one to prepare meals at home.

Furthermore, no studies to date have shown that weight reduction is effective in reducing blood pressure for long periods or for patients who are only slightly overweight.

Success in the long-term control of obesity, even with regimented programs using behavioral modification techniques is dismal.

Clinical Applications

Nutritional therapy of hypertension with low sodium or limited caloric diets or both often represents major changes in life-style that are not well tolerated by many patients. It is usually easier to convince patients to adhere to a pharmacologic regimen than to make changes in their diet.

Even for patients who are well motivated to follow such diets, it is difficult to do so because of the unavailability of processed foods that are low in sodium or limited in calories. It is practically impossible to adhere to such diets if many meals are eaten out of the home.

The Coordinating Committee of the National High Blood Pressure Education Program has recommend that "moderate sodium restriction should be routinely considered as a possible element in the treatment of all hypertensives."[44]

If it can be accomplished, limitation of dietary sodium to 2.0 gm daily may normalize blood pressure for many patients with mild hypertension (diastolic 90-104 mm Hg). It will augment the effects of antihypertensive drugs, including diuretics and will minimize diuretic-induced kaliuresis.

The antihypertensive effects of weight reduction are not nearly so well documented, and weight control is even more difficult to achieve and maintain than dietary sodium restriction. It appears that a meaningful decrease in blood pressure is not likely to result unless patients are more than 20 percent above their ideal weight and lose at least 20 pounds.

Too often physicians and patients postpone pharmacologic treatment of hypertension indefinitely while the patient tries in vain to lose weight and/or limit dietary sodium. Now that the Hypertension Detection and Follow-up Study has documented that drug treatment reduces mortality and cardiovascular morbidity for patients with diastolic blood pressures between 90 and 104 mm Hg,[45] we no longer have the option of procrastinating indefinitely with nutritional therapy that is not effective in reducing blood pressure.

Some patients prefer to try diet as initial therapy and this is a reasonable approach provided that hypertension is mild, asymptomatic, and uncomplicated, and the patient agrees in advance that pharmacologic treatment will be prescribed if blood pressure is not controlled (diastolic $<$ 85 mm Hg) within three to six months.

For patients with complicated or severe hypertension, nutritional therapy should be considered adjunctive to pharmacotherapy.

It has been my experience that most patients are not able to achieve effective dietary sodium or caloric restriction. Emphasizing this aspect of the therapeutic regimen may discourage some patients, make them feel guilty if they do not adhere to the regimen and cause embarrassment when the physician reprimands them for nonadherence. Many will choose to drop out of treatment programs altogether because of their fear of chastisement and hence the nutritional approach can be counterproductive.

Consequently, it is my practice to start therapy with an oral diuretic unless the patient specifically objects to medication or expresses a preference to try diet first. Many patients with mild hypertension will become normotensive on an oral diuretic without modification of dietary sodium and for this reason I do not routinely advise sodium restriction.

If the blood pressure does not become normal on the diuretic alone I usually estimate the patient's dietary sodium intake by measuring 24-hour urinary sodium excretion. If it is greater than 100 mEq/day, I suggest reducing dietary sodium to less than 100 mEq/day before deciding about the necessity of adding a second drug to the regimen.

Nutritional therapy of hypertension has a better chance of succeeding if both the patient and whoever is responsible for preparing meals at home are given extensive counseling by a knowledgable physician or a qualified nutritionist. Progress should be monitored by measuring 24-hour urinary sodium excretion, especially if blood pressure is not responding satisfactorily. If weight reduction is the goal, the patient should be seen at frequent intervals for measurement of blood pressure and body weight. Repeated dietary counseling is often helpful.

Nutritional therapy for hypertension would be much more appealing and widely prescribed if: a) More physicians were knowledgable in nutritional therapy and/or more nutritionists were available for counseling with patients and their families; b) successful behavioral techniques for motivating patients to adhere to diets were developed; and c) food processors could be encouraged to make widely available appetizing food products that are low in sodium and calories; and d) the sodium content was listed in a practical way for each food item in retail stores.

Summary

Although effective, nutritional therapy for hypertension is limited by the problem of patient adherence. If sodium or caloric-restricted diets or both are prescribed as initial therapy, it is incumbent upon the physician to be certain that blood pressure is normalized within a reasonable period of time and to prescribe appropriate medication if it is not.

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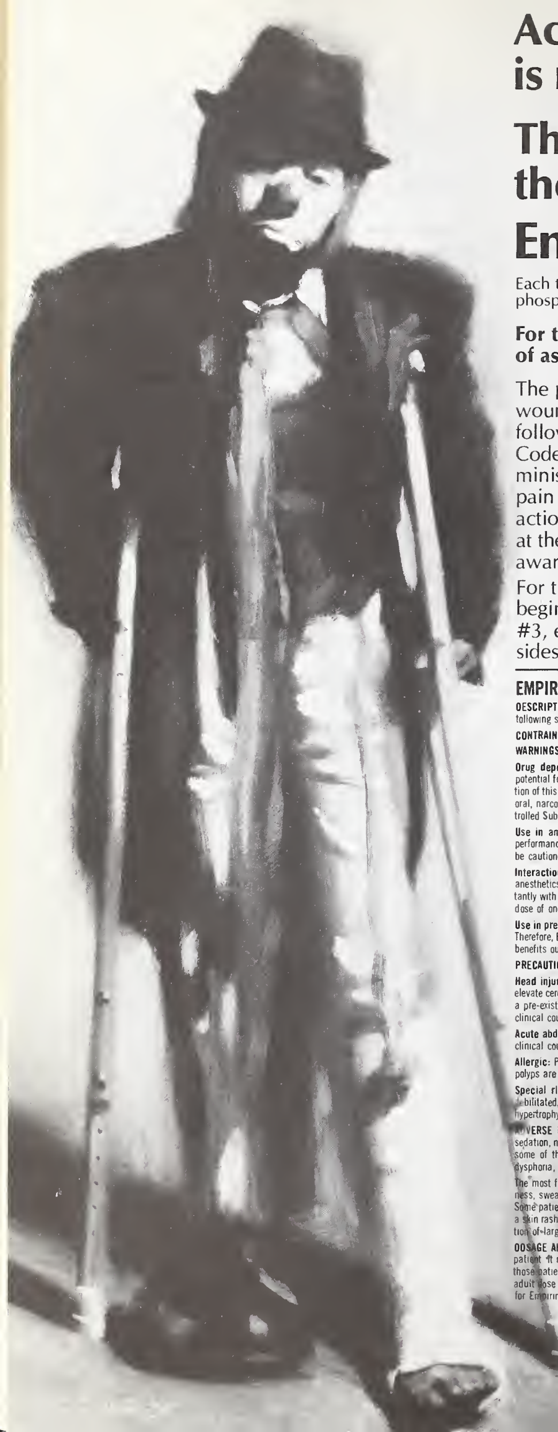

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Special risk patients: Empirin with Codeine should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture, peptic ulcer, or coagulation disorders.

ADVERSE REACTIONS: The most frequently observed adverse reactions to codeine include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down Other adverse reactions include euphoria, dysphoria, constipation, and pruritus.

The most frequently observed reactions to aspirin include headache, vertigo, ringing in the ears, mantal confusion, drowsiness, sweating, thirst, nausea, and vomiting. Occasional patients experience gastric irritation and bleeding with aspirin. Some patients are unable to take salicylates without developing nausea and vomiting. Hypersensitivity may be manifested by a skin rash or even an anaphylactic reaction. With these exceptions, most of the side effects occur after repeated administration of large doses.

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics. Empirin with Codeine is given orally. The usual adult dose for Empirin with Codeine No. 2 and No. 3 is one or two tablets every four hours as required The usual adult dose for Empirin with Codeine No. 4 is one tablet every four hours as required.

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How Do We Feed the Person with Diabetes?

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When the title of this article was suggested to the authors, we were first tempted to change it. Surely, it is demeaning to the patient, and unlikely to inspire compliance with our recommendations, if we take the attitude that we are going to "feed" him. Even if we do not take the literal meaning of the word, it implies passivity on the part of the patient: we feed; he eats. We order; he complies. Ultimately, we felt that the title was a good one, because it lets us make the first important point in dietary management of diabetes: we do not feed the diabetic patient, but teach him and encourage him to feed himself. The job of the physician (and the dietitian or nutritionist) is to guide the patient into making the proper choices.

Having eliminated the idea that we feed the diabetic patient, we must now get rid of the notion of a "diabetic diet." The American Diabetes Association, in its recent dietary recommendations for individuals with diabetes mellitus, states:

> For all healthy individuals, nutritional requirements are basically the same, varying primarily in amounts during the various stages of the life cycle. The dietary recommendations for diabetic persons are, in most respects, the same as for nondiabetic persons and are based on sound principles of nutrition.[1]

Basically, this quotation says that, in most respects, the "diabetic diet" should not differ from a nutritionally sound diet for a non-diabetic person. In many ways, then, the question what do we feed the diabetic person" becomes "what do we feed anyone who requires, or asks for, a sound diet." One guideline, of course, is the "Recommended Daily Allowances" (RDA's) for various nutrients, as determined by the Food and Nutrition Board of the National Academy of Sciences. These recommendations are, however, primarily designed to prevent nutritional deficiencies, and do not consider certain other known, or suspected, relationships between diet and health.

A set of dietary "goals" has been proposed by the U.S. Senate Committee on Nutrition with the aim of improving overall health as it relates to eating patterns,[2] and is listed in Table 1. While many authorities do not accept these goals in their entirety, or question whether there are adequate data to support them,[3] they nevertheless serve as a useful basis for discussing the dietary needs of the diabetic patient. If they are applicable to the person with diabetes, this enables us to take a very positive approach with our diabetic patients; namely, that their diet should not impose any unusually harsh restrictions on them. Rather, we are only asking them to eat in the way we (or, at least, the U.S. Senate committee) think all persons should eat to maintain good health. There are, of course, additional considerations for *some* persons with diabetes; we shall discuss these later.

Table 1

DIETARY GOALS FOR THE UNITED STATES

1. To avoid overweight, consume only as much energy (calories) as is expended; if overweight, decrease energy intake and increase energy expenditure.
2. Increase the consumption of complex carbohydrates and "naturally occurring" sugars from about 28 per cent of energy intake to about 48 per cent of energy intake.
3. Reduce the consumption of refined and processed sugars by about 45 per cent to account for about 10 per cent of total energy intake.
4. Reduce overall fat consumption from approximately 40 per cent to about 30 per cent of energy intake.
5. Reduce saturated fat consumption to account for about 10 per cent of total energy intake; and balance that with polyunsaturated and mono-unsaturated fats, which should account for about 10 per cent of energy intake each.
6. Reduce cholesterol consumption to about 300 mg a day.
7. Limit the intake of sodium by reducing the intake of salt to about 5 gm a day.

From Dietary Goals for the United States, 2nd ed.[2]

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Insulin-dependent and Non-insulin-dependent Diabetes

A recent trend in diabetology is to avoid such terms as "juvenile-onset diabetes," "adult-onset diabetes," "brittle diabetes," and so on. Instead, idiopathic diabetes mellitus is described as "insulin-dependent" or "non-insulin-dependent."[4] A person with diabetes is insulin-dependent if insulin is necessary to avoid ketosis and, ultimately, maintain life. Other persons may require insulin to treat symptomatic hyperglycemia but, if insulin is withheld, will not generally develop ketoacidosis. Such patients, even if treated with insulin, have non-insulin-dependent diabetes. This distinction is not trivial, but is of utmost importance in choosing appropriate dietary therapy.

For the obese non-insulin-dependent diabetic individual, there is ample evidence that weight reduction alone is effective in reducing hyperglycemia.[5,6] In part, this is probably due to reversal of insulin-resistance produced by the effect of obesity on insulin receptors.[7,8] However, in many patients, reduction of caloric intake will reduce plasma glucose levels even with no or little weight loss,[5] indicating that other mechanisms must also be operative.

In addition to control of calories, certain other factors may be important in the meal plans of certain persons with diabetes. These are listed in Table 2. The non-insulin-dependent person usually does not need to eat meals on a rigid schedule as long as total calories for the day are controlled.[9] If such a patient is treated with insulin, it is generally best to encourage him to eat regular meals each day, to avoid hypoglycemia. Such patients generally produce substantial amounts of endogenous insulin,[10] which is supplemented by injected insulin. Endogenous insulin secretion can decrease for a smaller than normal meal, so such patients generally need not rigorously try to consume meals at exactly the same time, or of exactly the same size, on every day. The patient who is treated with diet alone may be able to utilize his capacity to secrete endogenous insulin more efficiently if food intake is divided into three meals a day, rather than a single larger meal. Apart from this, there is no need to specify the size or content of each meal. It is best to avoid simple carbohydrates (glucose and sucrose) as these will cause plasma glucose to rise more rapidly than will complex carbohydrates,[11] and neither injected insulin nor the limited ability to secrete endogenous insulin can consistently control this.

Table 2

Factors which may be important in diet prescriptions for persons with diabetes:

1. The need to control calories.
2. The need for appropriate timing of meals.
3. The need to control size of meals.
4. The need for appropriate amounts and types of carbohydrate, protein and fat.
5. The need, if any, for special sweeteners or "diabetic" foods.
6. Other medical conditions requiring special dietary planning.
7. The need to individualize meal plan to the life style of the patient.

The person with insulin-dependent diabetes, on the other hand, does not secrete significant amounts of endogenous insulin. Thus, he must rely on a careful balance between food and injected insulin, and does not have the "buffering" ability of endogenous insulin secretion to correct for any day-to-day, or meal-to-meal, fluctuations in food intake. If meals and insulin are very precisely balanced, timing of meals is quite important, because a delay in a meal may lead to an insulin reaction. We do not prescribe snacks for all patients on a routine basis, but add them as needed to prevent between meal or night-time hypoglycemia. Some patients may need a snack shortly before exercise. Best dietary compliance can often be achieved if suitable snacks are also allocated at times when they are socially desirable, e.g. after-school, during scheduled coffee-breaks, or at bed time. The calories of the snack must, of course, be included in the daily calculated caloric allotment.

Diet composition is also important for the insulin-dependent diabetic, for carbohydrate calories will cause a greater rise in plasma glucose, and require more insulin, than fat calories, with protein calories being intermediate. In order to maintain day-to-day consistency in the carbohydrate, protein and fat at each meal, while allowing sufficient variety in foods to make meals appetizing and nutritionally balanced, "exchange" lists are generally used to state the diet prescription.[12] We shall not discuss in detail how such exchange-list diets are constructed; excellent manuals are available for this.[13] The physician is encouraged to refer patients needing such diets to a qualified diet counselor, who will have experience both in planning such diets and in instructing patients in their use.

The insulin-dependent patient will also need instructions on adjusting his diet during minor illnesses, when he may not be able to consume his regular meals.

How Much Carbohydrate, and What Type?

Recently, there has been an important change in attitudes towards the proper amount of carbohydrate in the diabetic diet. Traditionally, carbohydrate restriction has been an important part of diabetes therapy in the United States and Western Europe, although there has been little objective evidence of its efficacy. Clinicians in certain Eastern and tropical countries have long known, in contrast, that both maturity-onset and adult-onset diabetes can be satisfactorily controlled on diets containing almost twice as much carbohydrate as is found in standard diets of the West.[14] The exact percentage of carbohydrate which is optimal in the diabetic diet is yet to be determined. Kiehm et al[15] have shown that a diet consisting of 75% carbohydrate can improve diabetic control, if the carbohydrate is rich in dietary fiber (see below). In contrast, a "typical" American diet contains about 46% of its calories in carbohydrate, with 24% of calories as sugar and 22% as complex carbohydrates. The dietary goals of the Senate committee (Table 1) urge a diet of 58% carbohydrate, 48% complex and 10% simple. Thus, the U.S. dietary goals are consistent with current trends in diabetic diets for all types of diabetes.

Increasing the percentage of calories which come from carbohydrate has another benefit: the calories from fat are correspondingly reduced. If carbohydrate is restricted, needed calories can come only from protein or fat. As vegetable protein is usually accompanied by carbohydrate, this is a limited source of calories in the carbohydrate-restricted diet. Thus remaining calories must generally come from animal fat. Although there is disagreement on this point, most authorities feel that a diet high in animal fat prediposes to atherosclerosis. Such a diet should, therefore, be discouraged for the diabetic individual, who is already at increased danger of atherosclerotic cardiovascular disease. By permitting increased carbohydrate in the diet, we are able to lower the amount of fat, and increase vegetable sources of protein.

Some early studies expressed concern because high carbohydrate diets increased serum triglyceride levels. However, these studies gave high carbohydrate diets as formula feedings, where simple sugars comprised most of the carbohydrate. Subsequent studies, which emphasized complex carbohydrates, actually produced lower triglyceride levels, as well as decreased serum cholesterol.[16]

We frequently hear, from our less affluent patients, that they "cannot afford" a diabetic diet. The ability to increase the amount of high-carbohydrate, low cost food, may prove helpful in this regard. However, because this population group also has a high incidence of obesity, a limited food budget is still a problem, because many foods with low caloric and a high satiety value, such as fresh fruits and vegetables, have a high cost or are only seasonably available.

The Role of Dietary Fiber in Treating Diabetes

Although most persons are familiar with the concept of dietary fiber, or "roughage," it has been difficult to find a definition of fiber which is acceptable to all nutritionists. From a physiologic standpoint, it has been defined as all food ingested by a monogastric animal (e.g., man) that reaches the large intestine essentially unchanged. Thus, the term includes a wide variety of plants whose storage carbohydrates and cell walls are resistant to digestive enzymes.[17]

A number of studies suggest that dietary fiber may influence blood glucose levels. Epidemiologic studies by Burkitt et al[18] and by Trowell[19] have suggested that populations having a low dietary fiber content have a higher incidence of diabetes. Jenkins et al[20] showed that addition of two particular types of fiber (guar and pectin) to standardized meals results in significant reduction of postprandial glucose and insulin levels in non-diabetic subjects as well as in non-insulin-requiring diabetics. Insulin-dependent patients also showed a lowering of postprandial glucose levels.[21] Kiehm et al have shown that a high fiber, high carbohydrate diet could lead to a decreased requirement for sulfonylureas or insulin in many diabetic patients.[15]

To separate the effects of increased carbohydrate from those of increased fiber, Miranda and Horwitz studied eight insulin-dependent diabetic patients on two different diets, one of which contained 3 g of crude fiber and the other 20 g.[22] Calories and percentage of carbohydrate, fat and protein were constant on both diets. The two diets were given, in random order, for 10 days each, and each patient's insulin dose was kept constant throughout the study. The source of dietary fiber varied from patient to patient, depending on food preferences, but in most patients was a commercially available high fiber bread in which the principal fiber is cellulose. Mean plasma glucose throughout the day was significantly ($P<0.001$) lower on the high fiber diet (120.8±10.1 mg/dl) than on the low fiber diet (169.4±11.7 mg/dl). Differences were found only in postprandial values, with fasting plasma glucose values similar on both diets (Figure 1). Significantly more insulin reactions were seen on the high fiber diets. Although this study did not establish the mechanism by which high fiber diets lower plasma glucose, caloric malabsorption was unlikely as no patient had a significant weight change or symptoms of malabsorption.

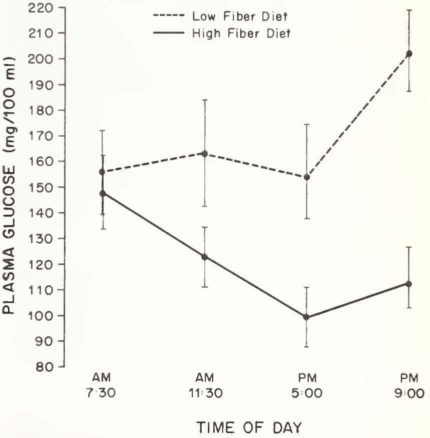

Figure 1

Mean (±SEM) plasma glucose levels on high and low fiber diets. Modified from Miranda and Horwitz[22] and reproduced with permission.

It seems clear that, in certain standardized situations, increased dietary fiber may significantly lower the plasma glucose concentration. Studies up to 15 months in duration have shown that this effect is sustained in most, but not all, patients.[23] However, certain types of fiber may lead to decreased absorption of calcium, zinc, magnesium and phosphorus, and lower serum levels of both iron and ionized calcium. Long term studies are needed to determine whether these findings are clinically important.

Because high fiber diets are used in the treatment and prevention of many diseases other than diabetes (reviewed in references 24 and 25), we should not deprive the diabetic patient of their benefit. If diabetic control happens to improve, so much the better. The patient and physician should be aware that the dose of insulin or oral agents may need to be decreased when a high fiber diet is instituted. Patients may begin such diets without medical advice; this could lead to problems in a person with previously well-controlled diabetes.

Sweeteners: Natural and Artificial

The need to restrict glucose and sucrose in the diabetic diet is commonly accepted, but there are surprisingly few data supporting this practice. Because the simple sugars are rapidly absorbed, they produce peak hyperglycemic levels greater than those seen with other food substances. Because repeated hyperglycemia may damage small blood vessels, nerves, and the lens of the eye, it is probably best for the diabetic patient to avoid these sweeteners as much as possible. Fresh fruits and fruit juices are accepted by most diabetologists, as suitable foods in spite of the high concentration of glucose or sucrose in some of them.[26] Simple sugars are frequently found in high caloric foods, and thus may aggravate obesity. They have been definitely implicated in the pathogenesis of dental caries. Thus, the U.S. Dietary Goals suggest limitation of simple sugars by all individuals, diabetic or non-diabetic.

Sweetness can be a habit. It may take a person years of behavior modification to alter the craving for "something sweet." He may never adjust to "doing without." With that in mind, it may be for the patient's benefit if some type of sweetener is available to him. Much controversy exists concerning sweeteners such as saccharin, cyclamates, sorbitol, xylitol, aspartame, and fructose.

Fructose, xylitol and sorbitol are all naturally occurring substances which can be used as sweeteners. Fructose and xylitol are about as sweet as sucrose, and have the same number of calories per gram. In poorly controlled diabetes, or during fasting, these sugars are generally metabolized to glucose and so may further elevate the plasma glucose level. In well controlled diabetes, however, they may be metabolized in the Krebs cycle or stored as glycogen in the liver, and do not increase the blood glucose concentration as much as glucose or sucrose do. For this reason, fructose and xylitol may be useful sweeteners in the well controlled diabetic person. Xylitol may also help reduce dental caries. Sorbitol is somewhat similar, but is less sweet. It is also less well absorbed so may lead to intake of fewer calories but, for the same reason, can cause osmotic diarrhea. Because of their caloric value, these sweeteners must be included in calculation of food intake, and they are probably of no special value in the obese diabetic person for this reason. For the insulin-dependent patient, these sugar substitutes may be of use, but there is virtually no long-term information on their safety in such individuals, and all authorities agree that more studies are needed.[26,27,28]

Aspartame presents a different situation. This is a dipeptide (L-aspartame-L-phenylalanine methyl ester) which enters normal pathways of amino acid metabolism. Therefore, it is potentially less likely than other synthetic sweeteners to have serious toxicity; however, there are still limited data on this point. Although on a weight basis it contains as many calories as sucrose, it is 180 times as sweet, so only minute quantities are used. Short term studies show it does not affect diabetic control in non-insulin-dependent patients.[29] At the time this article was prepared, aspartame was not yet approved by the Food and Drug Administration (FDA), but this approval is expected shortly. Further studies are needed to determine its usefulness for all types of diabetic patients, but presently there are no known contraindications to its use in diabetes.

Saccharin and cyclamate are synthetic substances which are both rather controversial at present. Cyclamates are currently not available in the U.S. at this time, although many authorities believe the data relating cyclamates to cancer are actually less convincing than those for saccharin. Saccharin is a synthetic substance derived from toluene, and is over 400 times as sweet as sucrose. Saccharin may be added to many foods and helps to satisfy the human craving for sweetened foods. Prior to April, 1977, saccharin was considered to be a generally acceptable non-nutritive sweetener available for the diabetic person. At that time, however, a number of studies suggested that ingestion of saccharin may be associated with bladder cancer, at least in animals, causing the FDA to consider banning the substance. Since the "quality of life" of many people benefitted from saccharin, The American Diabetes Association began an investigation in July, 1977, and organized a committee of distinguished scientists to review all relevant data. The committee examined twelve human epidemiological studies, of which eleven showed no relationship between artificial sweeteners and the risk of urinary bladder carcinoma. Although one study did indicate a risk of bladder carcinoma with saccharin usage,[30] this study has been criticized for defects in methods and analysis.[31]

The FDA concluded that available studies lacked sensitivity for weak carcinogens and that the evidence at present neither supports or refutes the hypothesis that the use of artificial sweeteners, specifically saccharin, increases the risk of bladder cancer.[32] A panel of the National Academy of Sciences has, however, concluded that saccharin does present a potential, but low, risk of carcinogenesis in man.[33]

Associations of bladder cancer with cigarette smoking and coffee drinking have also been suggested. Of the three, the use of saccharin seems to have the lowest risk for the development of bladder cancer.[32] The American Diabetes Association concluded that the saccharin controversy is not resolved. At this time, the legislative status of saccharin remains uncertain. Considering the available evidence, we feel it is prudent to restrict saccharin usage to those patients for whom the apparent benefits outweight potential risks.[34] Its use by children and pregnant women should be discouraged.

Diabetic persons often purchase foods labeled "diet," "dietetic" or "diabetic" and mistakenly believe that these products may be used freely in their diets. These special foods are sometimes meant not for the diabetic, but solely for restricting calories. In general, the person with diabetes can eat most of the foods the non-diabetic person eats, and need not purchase special foods. Special "diet" foods are not recommended with the exception of water-packed fruits and artifically sweetened soft drinks. The "dietetic" foods may have nearly the same calories, less nutritional value, and higher cost than regular foods. They obviously increase the patient's total calories for the day if used in addition to the prescribed diet, and alter the carbohydrate, protein and fat distribution.

Special Problems of the Obese Diabetic

At this point, the need for the obese diabetic patient to lose weight should be quite clear. Also, the freedom allowed the obese, non-insulin-dependent patient with regard to timing and composition of meals is apparent. What we have not yet discussed is the most difficult question: how do we get our obese diabetic patients to lose weight? Unfortunately, as every physician realizes, there is no easy answer to this.

In general, most of the "balanced diet" approaches to a reducing diet can be used in diabetic patients. These meal plans are safe and nutritionally sound, although vitamin supplements should be given if total calories are below 1000-1200 calories. Thus, methods based on "will power" or behavioral modification techniques, and group processes (such as TOPS or Weight Watchers®), can be of potential use. Increased exercise, appropriate to the age and cardiovascular status of the patient, may prove useful in increasing caloric expenditure, promoting greater overall health, and providing a better outlook on life. In some patients, exercise may replace eating as a way of occupying time.

Various other approaches, not based on traditional nutritional principles, have sometimes been advocated. These include such techniques as total fasting, the rice diet, the protein sparing modified fast, and jejunal-ileal or gastric bypass procedures. Although some of these approaches seem to be safe in qualified hands,[35] they should not be casually recommended. Without detailed knowledge of the specific nutritional and physiological consequences of each approach, these techniques can lead to significant complications and even death.

"Fad" diets come and go, depending on the nation's reading habits and television talk shows. Any discussion would be rapidly out of date. Unless the physician has the time and nutritional knowledge needed to carefully analyze each diet about which his patients might ask, we feel it is best to rely on the advice of a qualified nutritionist to determine whether the diet in question is nutritionally balanced. If so, such a diet may help provide additional patient motivation. The diabetic patient is best steered away from any diet departing from proven nutritional concepts until the safety of such a diet has been demonstrated in diabetes.

Conclusions

We have tried to demonstrate that an appropriate diet for non-insulin-dependent persons, comprising the large majority of diabetic patients, need not be any different than the diet proposed as ideal for most persons by the U.S. Senate Select Committee on Nutrition. Only reasonable adherence to regular meal times needs to be added to the Senate recommendations (Table 3). By pointing out to such patients that their diet is not "special," but is good and healthy for the entire family, we may be able to motivate our patients into better dietary compliance. Weight loss is still paramount in most of these patients, and considerable encouragement by the physician, dietician, and patient's family is necessary. For this type of diabetic person, many common weight-reduction programs can be useful.

Table 3

DIET INSTRUCTIONS FOR DIFFERENT TYPES OF DIABETES

Non-insulin-dependent diabetes

1. Follow the "Dietary Goals for the United States"
2. Divide food into 3 meals a day (with snacks if needed)

Insulin-dependent diabetes

1. Follow the "Dietary Goals for the United States"
2. Maintain consistent timing and composition of meals (generally, using a diet based on "exchange" lists)
3. Learn to adjust diet appropriately for minor illnesses, special occasions, and hypoglycemic reactions

The individual with insulin-dependent diabetes must accept greater restrictions regarding the timing and size of each meal. He or she must also devote more time to learning various aspects of diet therapy. Nevertheless, the basic meal plan can remain consistent with the Dietary Goals for the United States (Table 3), and the patient can again be reassured that his diet remains a healthy one which his family and friends should also be eating.

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Hospital Malnutrition: A Specter or a Certainty?

ROBERT L. RUBERG, M.D.

The development of a reliable technique for total parenteral nutrition[1] in the 1960s sparked a revolution in the nutritional care of hospitalized patients. Fifteen years ago, physicians paid little attention to patients' nutritional problems. Medical educators generally buried nutrition instruction in easily-forgotten elementary physiology courses, and clinical nutrition problems were considered rare and out of the physician's realm of expertise. Now we find an almost total reversal of attitude: hospital malnutrition is reported to be extremely common; "The Skeleton in the Hospital Closet"[2] has been dragged out and spotlighted for all to see. Nutritional assessment has been urged for all hospitalized patients; and special nutrition techniques have been developed and emphasized to the point that a physician may feel guilty if his patient is *not* receiving tube feeding, or elemental diet, or total parenteral nutrition, or the latest form of dietary therapy.

Fortunately, a few recent studies have presented hard data regarding the incidence of nutritional problems and the importance of dietary therapy. We will examine some of these studies in an attempt to gain perspective on the issue of hospital malnutrition by answering four important questions: 1) How prevalent is malnutrition in hospitals? 2) How significant is malnutrition in an individual patient? 3) How can malnutrition be most easily recognized? 4) How is malnutrition best treated in the hospital?

Prevalence of Malnutrition

Some of the earliest efforts to call attention to the number of malnourished patients "hidden" in hospitals came from Butterworth.[2] He reviewed records of 100 hospitalized patients and found widespread evidence of deficient nutritional care, inadequate initial patient assessment (e.g. lack of recording of even height and weight), improper feeding techniques, and significant hypoalbuminemia (37% of patients). He concluded that little attention was being paid to nutritional status and that an alarming number of patients became *more* malnourished owing to improper management *in the hospital.*

Bistrian, Blackburn, et al[3] studied the nutritional deficits of general surgical patients in 1974. Among all surgical patients at an urban municipal hospital, they found what they judged to be moderate to severe protein calorie malnutrition in about half the patients. These investigators extended the nutritional assessment beyond the simple determinations of height, weight, and serum proteins to include *anthropometric* measurements not previously made in hospitalized patients. As a result they were able to demonstrate this "striking prevalence" of protein calorie malnutrition not previously recognized.

In 1976, the same investigators examined general medical patients, and found slightly different but roughly comparable results.[4]

The physician practicing in a municipal hospital was thus forewarned of the likely high incidence of malnutrition in his patients, but what about the physician practicing in a more affluent setting? Weren't his patients much less likely to have similar deficiencies? This notion was dispelled by a study presented by Willcutts in 1977.[5] Using a very thorough form of nutritional assessment, he reported a *65%* incidence of moderate to severe malnourishment in "an affluent suburban community hospital." The malnutrition was "subclinical" in two-thirds of the patients, so cursory assessment would have detected only a small proportion of these problems.

Finally, Mullen[6] et al. in extensive studies in a Veterans Hospital found that 97% of patients had at least one abnormal nutrition parameter.

One might conclude that if enough studies were done, almost every patient would exhibit *some* value out of the normal range on sophisticated nutrition testing. Clearly, the critical issue is not merely the presence of an abnormal result, but the correlation of such a finding with the clinical results of medical or surgical therapy.

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Significance of Malnutrition

Several recent studies attempted to link abnormal nutrition parameters with surgical complications. Meakins[7] studied surgical patients at high risk for developing infection. Looking at delayed hypersensitivity (a proved measure of nutritional status[8]), he found a compelling relationship between anergy (lack of response to skin tests antigens) and surgical complications. Patients who had normal skin test reactivity had a 21% sepsis rate and a 2.1% mortality rate, whereas patients who were anergic or relatively anergic had a 65% sepsis rate and 74% mortality. The correlation of this single nutrition-related parameter with complications of surgery was dramatic.

Mullen[6] also analyzed a series of nutritional parameters and their relationship to operative complications in the general surgical veterans population. He found that patients with a serum albumin level below 3.0 gm/dl had twice the surgical complication rate of those with levels above 3.0 gm/dl, and patients with negative skin tests had twice the incidence of complications experienced by those with positive tests. Serum transferrin levels were found to be the most sensitive predictors of surgical problems: patients with transferrin levels below 220 mg/dl had *five* times the complication rate of those with transferrin levels above 220 mg/dl.

Further studies by Mullen resulted in a formula useful in predicting the chances of surgical complication based exclusively on the patient's nutritional status. This "Prognostic Nutritional Index" was calculated:

$158 - 16.6(ALB) - 0.78(TSF) - 0.20(TFN) - 5.8(DH)$

where ALB = albumin in gm/dl; TFN = transferrin in mg/dl; TSF = triceps skin fold in mm; and DH = delayed hypersensitivity graded 0 = nonreactive, 1 = <5 mm response; 2 = >5 mm response. Mullen's classification was as follows: low risk of complications, PNI <30%; moderate risk, 30-59%; and high risk, >60%.

The foregoing studies apply exclusively to surgical patients. The significance of malnutrition in the medical patient is much less well studied and perhaps harder to document. As an example, the importance of nutritional status for success of cancer chemotherapy is currently under investigation. Preliminary studies[10] suggest that the cachexia of the cancer patient may contribute to failure of chemotherapy, and that special techniques such as total parenteral nutrition can reverse nutritional deficits in the cancer patient and thus improve significantly the chances for treatment response.

These various studies all strongly suggest the importance of good nutritional state in the successful outcome of medical or surgical therapy. Patients with isolated nutritional deficits or mild abnormalities probably are at little additional risk during hospital treatment; but when the deficit becomes significant, the consequences become significant. The easy identification of the patient at risk and the appropriate form of therapy thus become important issues.

Identification of the Malnourished Patient

Part of the change in physicians' approach to malnutrition is the improved ability to recognize the malnourished patient. Fifteen years ago, most physicians used an "eyeball" assessment technique: if the patient looked thin and was below the ideal weight for his height, he was malnourished. Now a number of assessment techniques can be used.

Perhaps the most thorough but complex of these techniques for nutritional assessment is the method of Blackburn,[11] utilizing an extensive profile of nutrition-related parameters. These are outlined in Table 1. This form of assessment provides a detailed and accurate picture of a patient's nutritional state. But clearly, this method is expensive and time-consuming, therefore probably not applicable to the majority of hospitalized patients.

Table 1

COMPLEX NUTRITIONAL ASSESSMENT*

1. Height/weight index
2. Creatinine/height index
3. Triceps skin-fold thickness
4. Mid-arm muscle circumference
5. Serum albumin
6. Serum transferrin or total iron binding capacity
7. Total lymphocyte count
8. Skin tests for delayed hypersensitivity

*Adapted from: Blackburn GL, Bistrian RR, Maini BS, et al.: Nutritional and metabolic assessment of the hospitalized patient. J Parent Ent Nutr 1:11, 1977

A simpler form of nutritional assessment has been used by Copeland and Dudrick.[12] This evaluation is based on only three parameters, each quite simple to measure (Table 2). If a patient has two or more of these abnormalities, the authors regard this as significant and recommend that nutritional therapy be undertaken *prior* to surgical or medical therapy if possible. Specific deficits can then be more carefully documented using the Complex Nutritional Assessment (Table 1).

Table 2

SIMPLE NUTRITIONAL ASSESSMENT*

1. Recent unintentional weight loss of 10 lbs or more
2. Serum albumin less than 3.4 gm/dl
3. Negative skin tests

*From Copeland EM, MacFadyen BV Jr, Dudrick SJ: Effect of intravenous hyperalimentation on established delayed hypersensitivity in the cancer patient. Ann Surg 184:60, 1976

Each of these methods for nutritional assessment requires time to complete, particularly the determination of immune competence measured by skin tests. Recently, Seltzer[13] described a technique which permits an "Instant Nutritional Assessment" (Table 3). This "instant" assessment is achieved by determining the serum albumin level and calculating the total lymphocyte count from the total white blood cell value and the percentage of lymphocytes in the differential. These values are frequently readily available as part of routine admission studies. A serum albumin lower than 3.5 gm/dl and/or a total lymphocyte count of less than 1500 per cubic millimeter can be correlated with increases in complications and mortality. Again, abnormalities in the "instant" assessment can be confirmed and pin-pointed with a subsequent complete assessment of all parameters.

Table 3

INSTANT NUTRITIONAL ASSESSMENT*

1. Serum albumin
2. Total lymphocyte count

*From Seltzer MH, Bastidas JA, Cooper DM et al.: Instant nutritional assessment. J. Parent Ent Nutr 3:157, 1979

When the patient with nutritional deficits has been identified, a variety of therapeutic techniques may be employed.

Nutrition Therapy Techniques

The physician may choose from a variety of techniques, each of which has advantages and disadvantages, indications and contraindications. Because of the early dramatic success of intravenous hyperalimentation (central TPN), many clinicians began to use this method for a wide variety of clinical problems, even when simpler and less risky methods of feeding would have been adequate. The effectiveness of alternate feeding techniques came into clearer focus with refinements in enteral methods and the development of peripheral vein nutrition programs. But, the central TPN technique still has broad applicability and is clearly life-saving in many clinical situations. Description of the steps in each of the feeding methods can be easily found in several recent review articles. The following discussion focuses principally upon rational choices between techniques rather than the technical details of each method.

A number of different feeding methods are available foı use in hospitalized patients (Table 4). In general, choice of feeding method should progress from oral diets to central venous feeding; oral diets are preferable to tube feedings, and tube feedings to intravenous techniques. Despite its dramatic successes, total parenteral nutrition should *not* be used unless feeding via the gastrointestinal tract is inadvisable (e.g., GI tract fistula), inadequate (e.g., massive burn), or impossible (e.g., bowel obstruction).

Table 4

ROUTES FOR NUTRITION IN HOSPITALIZED PATIENTS

I. Oral diets
    a) standard diets
    b) specialized formulas
    c) supplemental feedings
II. Enteral tube feedings
    a) standard formulas
    b) "elemental" diets
III. Peripheral venous feeding
    a) "protein sparing" (peripheral amino acids)
    b) total parenteral nutrition - lipid system
IV. Central venous feeding
    a) total parenteral nutrition - glucose system

The patient whose oral intake is not satisfactory should be offered interval feedings of supplemental formulas. Although in some hospitals these extra feedings are specially prepared by hospital dietary services, many institutions have successfully used commercially-prepared, palatable formulas with an energy value as high as 1.5 cal/ml. Defined formula ("elemental") diets should be used only when absorption high in the GI tract is essential because of their much increased cost and somewhat unpleasant taste.

When a patient is unwilling or unable to ingest sufficient calories, the next "line of defense" is tube feeding. (Again, if the GI tract works, it should be used.) Recent advances that have made tube feedings more feasible even for seriously ill patients include: 1) newer dietary formulas that are "isotonic," not hypertonic; 2) improved small-bore tubes; 3) continuous feeding methods (as opposed to the older "bolus" method; and 4) special pumps for controlled continuous delivery. As a result of these improvements as well as aggressive rapid volume advancement, many more patients are now successfully fed through enteral rather than parenteral tubes.[14]

If enteral techniques are inadequate or inappropriate, intravenous (IV) methods become essential. The "original" IV system was the central venous technique[15, 16] using glucose as major energy source ("hyperalimentation"). This is still the most widely used technique, but several more recent developments offer alternatives under certain circumstances.

Peripheral venous infusion of amino acids alone may be useful to maintain nitrogen equilibrium in patients unable to eat. This technique is most applicable to patients who do not have nutritional deficits and whose need for intravenous feeding will not be prolonged (usually no more than ten days). Although positive nitrogen balance is rarely achieved, this technique prevents major nutritional deficits without use of a central venous catheter.

When lipid, instead of glucose, is used as a major calorie source, total parenteral nutrition can be achieved through peripheral venous infusion.[18] This technique is extremely useful in children and may be applicable in some adults; however, recent evidence suggests that when deficits are significant or stress is a factor, the lipid system is not as effective as the glucose system[19, 20] and the cost may be significantly higher.

For patients with major deficits, stress, or prolonged requirements for intravenous feeding, central venous nutrition is the only alternative. In many institutions this technique is preferred to any other peripheral method because of its universal applicability and the fact that only one method instead of three need be mastered. The central technique has an acceptably low complication rate[21] in light of the life-threatening clinical conditions which force its use.

Conclusions and Summary

In an examination of the justifications for recent interest in hospital malnutrition and the proliferation of nutritional support techniques, available evidence certainly suggests that malnutrition exists in a significant percentage of hospitalized patients. Although a disadvantaged patient population appears to have a very high incidence of nutritional deficits, one cannot assume that a more affluent population will be free of such problems.

The available information strongly suggests that malnutrition may seriously affect the outcome of medical or surgical therapy. By using currently available assessment techniques, the physician can determine which patients require nutritional therapy as a primary mode of treatment, and also identify patients who do not need nutritional manipulation.

A rational approach to nutritional therapy recognizes that the most complicated (and expensive) feeding method is not always the best. Other less risky or less expensive methods may be adequate or even preferable under certain circumstances. With the use of rational therapeutic methods, malnutrition should become less prevalent in our hospitals in the years to come, and the overall success of medical and surgical therapy should improve.

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Diet, Nutrition and Cancer

NATIONAL CANCER INSTITUTE*

Although no direct cause-effect relationship has been observed for nutrition and cancer in humans, numerous scientific studies suggest that dietary factors may affect the risk of the disease. Because many other variables also influence the occurrence of cancer, the exact role that diet plays remains unclear. The National Cancer Institute has undertaken a number of activities to explore the role of diet in the causation of cancer, but until definitive results of such studies become available, only tentative inferences are possible. Based on the incomplete evidence now at hand, the following would appear to be prudent interim principles:

- In general, excessive body weight should be avoided by maintaining a balance between caloric intake and proper exercise. The appropriate balance should be determined by each person in consultation with his or her physician, depending on body build and medical status.
- To facilitate control of body weight, and in view of the suggestive association between fat consumption and the risk of cancer, a high intake of fat should be avoided.
- A generous intake of dietary fiber would seem prudent, based on the reduced incidence of bowel cancer in human populations and experimental animals that has been associated under certain conditions with a high intake of dietary fiber.
- In addition to providing the minimal daily requirements, fatty acids, and protein, the diet should be well balanced, including fresh fruits and vegetables. Such a diet, on the basis of present knowledge, would not ordinarily be expected to require supplementation with additional minerals, vitamins, or other factors.
- Alcoholic beverages should be consumed only in moderation, in view of the high correlation between heavy alcohol consumption and an increased risk of certain types of cancer.

Additional background information on fiber, fat, other dietary constituents, and their relation to cancer, follows:

Background Statement:

Fiber

Diseases of the intestines, including appendicitis, diverticulosis, colonic polyps and colon cancer have been noted to occur with relatively low frequency in populations ingesting large amounts of fiber. These populations are usually found in less industrialized countries. When individual differences have been investigated between geographic areas, a high fiber intake has been correlated with larger, softer stools, more frequent defecation, and more rapid intestinal transit times. It has been theorized that these effects could result in a decreased duration of exposure of the colonic mucosa to carcinogens in the feces, as well as a relative decrease in the concentration of such carcinogens in the feces.

With the epidemiologic data as a basis, a number of researchers began investigating the fiber-cancer correlation in the laboratory. In one such study, rats were previously treated with a digestive tract carcinogen and then fed different amounts of cellulose. Those rats fed the least amount of fiber developed more intestinal tumors. In addition, the observed number of tumors decreased with the increase in dietary bulk. In other studies, increased dietary fiber resulted in a decrease in mutagenic activity in human feces.

Possible effects of dietary fiber on the enterohepatic circulation of bile salts may also occur. Since bile salts and fat degradation products have been implicated as colon carcinogens, binding or dilution of these by fiber may be of significance.

Dietary fiber is complex. There are vast differences in the sources and types of fiber. Fiber consists of plant wall and non-nutritive residues. Non-nutritive residues include all substances resistant to animal digestive enzymes. Some of these residues may be fermented by colonic bacteria and the subsequent products absorbed. Alternations in the initial fiber content of food may occur with its preparation.

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*Statement by Dr. Arthur C. Upton, former director of the National Cancer Institute, before McGovern Senate Subcommittee on Nutrition.

There are six subcategories of dietary fiber: cellulose, hemicellulose, lignin, pectin, cutin and gum. These vary in their physical and chemical properties, biologic activity, natural sources, potential side effects and availability. With this in mind, it becomes obvious that fiber experimentation is dependent on the specific types studied and that generalizations concerning fiber may not be possible.

Fats

A theory, currently held by many cancer investigators, is that the increase in cancer rates observed in animals on high-caloric diets may be due to the increase in fat in the diet rather than to the increase in total food consumption. A recent series of experiments showed that rats fed diets containing unsaturated fatty acids, like those found in olive oil and sunflower oil, had a greater number of cancers than those fed more saturated types of fat, such as butter and coconut oil. In human populations, both breast cancers and colon cancers have generally been associated with the level of consumption of animal fat, which is mainly saturated.

Several theories to explain the mode of action of dietary fat in carcinogenesis have been suggested in recent years. The most widely held is that fat in the diet has a "promotional" effect on the development of cancer. In other words, it does not cause cancer directly but somehow influences metabolic processes or normal cells to make them more susceptible to the development of cancer caused by other agents. It has also been proposed that fat—whether unsaturated or saturated—may act as a solvent to enhance the effect of other carcinogens. Fats also are known to change the metabolism of many tissues in humans, possibly affecting the relation of various hormones to tissue growth. The case for this is strongest for breast cancer, where hormonal environment has been shown to influence susceptibility to cancer.

Breast cancer strikes more women in the United States, Canada and Western Europe than any other form of cancer. Yet it is comparatively rare throughout the developing world. Some scientists have suggested that the fat content of today's diet in the industrialized countries alters the body's balance of sex hormones, which in some as yet undetermined way increases susceptibility to breast cancer.

Although Japanese women living in Japan seldom develop breast cancer, their risk of the disease increases when they move to the United States. Likewise, some populations within the U.S. have lower breast cancer rates. The Seventh Day Adventists are an example. One thing that the native Japanese and Adventists have in common is a 20 to 50 percent less intake of fat in their diet than the general population of the United States.

Research on the initiation of mammary cancer in animals has supported this association. Despite differences in type of quality of fat or various elements of experimental design, scientists have found consistently that a high intake of dietary fat increased the development of mammary cancer in rodents.

One hypothesis being studied is that the synthesis and secretion of the hormone prolactin is affected by the fatty acid composition of the breast fluid. High levels of fat in the diet appear to promote the secretion of prolactin, which is a hormone that regulates the growth, milk production and other functions of certain breast cells, as well as affecting the amount of circulating estrogen.

Besides altering the hormonal environment, there are a number of other ways in which dietary fat might lead to breast cancer. These include influence on the metabolism of chemical carcinogens, on cell membrane structure, and on the immune system.

Cancer of the colon and rectum accounts for some 15 percent of the total cancer burden in the United States, and is second only to lung cancer in the number of deaths each year. Like breast cancer, colo-rectal cancer is much more common in the developed Western countries than in less developed areas of the world, and the high levels of fat in the Western diet may conceivably be a factor. Some investigators have postulated that the low levels of fiber in the Western diet may also be important.

Current research indicates that a diet high in fat increases the amounts of bile acids and sterols excreted during digestion. These normal breakdown products may conceivably be converted into carcinogens by bacteria which are normally present in the colon. Although no such carcinogen has yet been isolated, the biochemical mechanisms by which intestinal bacteria might produce carcinogens have been elaborately studied in the laboratory.

Body Weight

Lean or underfed animals have been found to have a decreased incidence of spontaneous and induced tumors, as compared with normally fed controls. Recently, an expert panel convened by the American Society of Clinical Nutrition and the Association of American Physicians concluded that obesity increases the risk of death from heart disease and cancer; however, the panel noted that few controlled studies have been done on human populations, and that it is too early to establish a definite correlation between total caloric intake and the risk of developing cancer. Several studies have shown a relationship between obesity and at least two forms of cancer in women: cancer of the breast and cancer of the endometrium.

Naturally-Occurring Carcinogens

A number of substances that are mutagenic or carcinogenic for animals are present as natural constituents or contaminants of certain foods. Examples include safrole, various flavanoids, cycasin, and mycotoxins.

The contribution of such substances to the human cancer burden remains to be determined. In general, ordinary foods have not been studied thoroughly for carcinogens. In certain parts of the world where agricultural or dietary practices may expose populations to such materials in relatively large quantities, these naturally occurring carcinogens may conceivably account for a significant fraction of the cancer incidence. It is postulated, for example, that mycotoxin contamination of the diet may be a major causative factor in the high incidence of liver cancer in parts of Africa and Asia, where high temperature and humidity frequently cause food supplies to become moldy in storage.

Man-Made Food Additives and Contaminants

Of the hundreds of chemicals that are added to our food, few have been shown to be carcinogenic in animals, and at this point *none* have been conclusively shown to cause cancer in humans. It is important to note, however, that most food additives have not been carefully tested for carcinogenic effects. Most of the additives and other non-nutrient substances in our food supply have been manufactured and consumed in large amounts only in the last 20-to-30 years.

Saccharin, an artificial sweetener added primarily to diet beverages, is one of six substances that the FDA has sought to ban. It announced its intention to do so on April 15, 1977, but the Congress prohibited the ban and called for an in-depth study of the evidence that saccharin caused cancer in animals. That study was completed and reported in March, 1979, by a blue-ribbon panel of the Institute of Medicine and the National Academy of Sciences. It is entitled "Food Safety Policy—Scientific and Societal Considerations." The study reviewed the scientific evidence that saccharin is a carcinogen and drew the following conclusions: 1) saccharin should be considered a carcinogen in rats "of low potency relative to other carcinogens"; 2) however, saccharin also "promotes" the cancer-causing effects of some other carcinogenic agents in "appropriate test systems"; 3) therefore, it should be considered a potential carcinogen in humans, "but one of currently uncertain consequence and potency in comparison with other carcinogens." The study recommended a number of options concerning the fate of the commercial use of saccharin, ranging from an outright ban to permitting its use as a prescription drug.

In January 1978 the NCI and the Food and Drug Administration began a case-controlled Epidemiology Study of bladder cancer patients in five states and four metropolitan areas of the U.S. This study will seek to determine whether saccharin might play a role in bladder cancer in man.

Other additives potentially associated with carcinogenesis, such as nitrites, have not been banned, but their legally acceptable levels have been reduced. Nitrites are added to some foods to enhance flavor and color or inhibit bacterial growth. Nitrites may also be produced by bacterial reduction from ingested nitrates that occur naturally in foods. The gastric conversion of ingested nitrates or nitrites to nitrosamines, compounds of high mutagenicity and carcinogenicity, has been postulated as an etiologic factor for stomach cancer.

Other additives, such as butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT), are used as food preservatives. These compounds are antioxidants and they can inhibit the tumorigenic response to a number of chemical carcinogens in animals.

The cooking of food has itself been observed to be a possible source of carcinogens. Carcinogenic polycyclic hydrocarbons have been identified in the smoke and charred material on the surface of smoked or grilled meat. More recently, mutagenic pyrolysis*-products have also been isolated from the charred surface of such food. These observations are noteworthy in demonstrating that all of us are exposed to varying amounts of dietary mutagens and carcinogens in the course of normal everyday life. However, the significance of this exposure in terms of its potential contribution to our risk of cancer cannot be assessed on the basis of present epidemiological or experimental evidence.

Alcohol and Cancer

There is no conclusive proof that alcohol alone causes cancer in either animals or humans. But scientific evidence strongly suggests that excessive intake of alcohol, especially in combination with smoking or dietary deficiencies, may lead to cancer.

A number of cancers are more prevalent among heavy alcohol drinkers, including cancers of the esophagus, mouth, throat, larynx and liver. Alcohol and tobacco are both well established as strong risk factors for cancers of the mouth and throat.

Among its other effects, alcohol is an irritant to the lining of the throat, esophagus and stomach. When combined with the physical and chemical insults of tobacco smoke, alcohol may promote abnormal cell proliferation at those sites. Nutritional and immunological deficiencis are commonly associated with or exacerbated by excess alcohol ingestion.

Vitamins and Minerals

Just as there are substances that cause cancer, there may be substances that act on the body to prevent it. In this regard vitamin research has been of interest to cancer investigators. However, sufficient evidence is not yet available to advocate the supplemental use of vitamins in the prevention or treatment of cancer.

Vitamin C is of possible anticarcinogenic importance because of its interaction with ingested nitrites or nitrates. It is an active reducing agent and has been shown to inhibit nitrosamine formation in the gut.

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*Chemical decompensation of a substance by heat.

Another role for vitamin C as a chemopreventative has been suggested by a pilot study showing regression of rectal polyps in four of five treated patients with familial polyposis. These patients have a very high risk of colon cancer. A large clinical trial is now underway to determine whether daily doses of vitamin C can prevent colon cancer in patients with this inherited condition.

A second proposed role of vitamin C is that of a palliative and life-prolonging drug in "terminal" cancer patients. Unfortunately, this has not been confirmed in a well-designed, prospective clinical trial, in which vitamin C-treated patients showed no benefit over those treated with placebo.

The effectiveness of vitamin A and its analogues as active chemopreventive agents for common forms of epithelial cancer has been demonstrated in animals. Vitamin A analogues have also been introduced into clinical trials. If their effectiveness in human patients is substantiated, it is possible that vitamin A analogues may be of benefit in delaying or preventing cancer, especially in high risk groups. However, the significant toxicity of vitamin A and the lack of substantial clinical human data on its analogues preclude their general use at this time.

Along with vitamins, minerals in various amounts are crucial for the body's normal metabolism. As such, they also may play a role in carcinogenesis. Studies are underway in experimental animals on the roles that dietary zinc, selenium, and iron may play in the development of some cancers. At this time, however, very little definitive information exists about the importance of these and other trace elements for the development of cancer.

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Adjuvant Chemotherapy of Breast Cancer

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Assisted by the Office for Medical Applications of Research, NIH

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A Consensus Development Conference on Adjuvant Chemotherapy of Breast Cancer was held at the National Institutes of Health on July 14-16, 1980. Its purpose was to bring together practicing physicians, research scientists, consumers and others in an effort to reach general agreement on the concepts and results of adjuvant chemotherapy trials in breast cancer and their implications for medical practice.

A consensus development panel and members of the audience considered evidence presented on the following questions:

- Have clinical trials established the efficacy of adjuvant chemotherapy of breast cancer?
- Do the benefits of adjuvant chemotherapy clearly outweigh the risks?
- Should future adjuvant chemotherapy studies include hormonal manipulations?
- What is the role of adjuvant chemotherapy in Stage I patients?
- What is the role of adjuvant chemotherapy in post-menopausal patients?

The members of the panel included a patient and representatives from the many disciplines involved in the evaluation and treatment of breast cancer. The panel met following formal presentations and discussions to assess the issues based on the evidence presented. This summary is the result of its deliberations.

Introduction

Adjuvant chemotherapy of breast cancer means the use of cytotoxic drugs after primary therapy. The rationale for adjuvant chemotherapy is to eradicate occult metastatic disease which otherwise would be fatal.

The assessment of adjuvant chemotherapy must balance efficacy against toxicity. The basic measure of therapeutic benefit is patient survival with acceptable quality of life.

Primary breast cancer is a heterogeneous disease with varying potentials for metastatic relapse and response to adjunctive drug therapy. Currently, three critical variables are used in planning adjuvant chemotherapy trials: involvement of the axillary lymph nodes, menopausal status and estrogen receptor levels. Three axillary lymph node categories are commonly accepted as prognostically important: negative axillary nodes, one to three positive axillary nodes and four or more positive nodes. These three categories strongly predict the risk of relapse after appropriate local treatment.

These three nodal subsets, when combined with the menopausal status (pre- or post-) and estrogen receptor (ER) status (positive or negative), result in 12 prognostic subsets. These subsets form the basis for planning additional clinical trials, and it is only from these trials that the best strategy for improved patient care will emerge. Adequate analysis of an adjuvant chemotherapy trial must consider whether enough data exist for one or more subsets to establish the role of that trial in assessing—and possibly modifying—current medical practice.

In general, the merits of a new or modified adjuvant treatment regimen must be assessed through comparative clinical trials, which randomly assign patients to

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EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

alternative treatments. Such a study design helps assure that patients in each of the treatment groups are comparable.

If a clinical trial is to yield meaningful information, patients need to be followed for a sufficient period, so that long-term results may be evaluated. No simple standard for duration of followup can be set, because the importance of observed results depends on the nature of the patient group under study. For example, in order to provide meaningful information, patients with minimal, potentially curable disease have to be followed for a much longer time than do patients with advanced disease.

There are two types of toxicity associated with chemotherapy: acute and remote. The acute adverse effects relate to the immediate drug administration; remote adverse effects, which also can be chronic, can occur long after drug administration has ceased. Acute toxicities include bone marrow suppression, nausea and vomiting, loss of appetite, weakness, mouth ulcers and hair loss. The remote chronic effects to which the physician should be alerted include organ damage, such as Adriamycin-induced cardiomyopathy, sterility and the induction of second cancers due to the carcinogenic potential of some of the drugs used.

The length of time during which the patient is free of disease after treatment is important but frequently must be regarded as a preliminary indication of therapeutic results. The ultimate efficacy of treatment must be measured in terms of survival time, although the quality of survival must be taken into consideration.

Studies that report negative results, i.e., no significant differences, should not be regarded as failures. If the study initially posed important question(s), and the study was designed and executed properly, then any negative finding is an important contribution to knowledge.

It is desirable to examine the possible influences on therapeutic results by factors not anticipated in the original study design. However, a cautionary note is in order: retrospective observations based on small subgroups of patients may be misleading.

By definition, adjuvant chemotherapy is drug treatment added to adequate local excisional therapy. The adjuvant chemotherapy trials reported to date have employed radical or modified radical mastectomy. Future trials may involve lesser surgical procedures, but the impact of lesser surgery on adjuvant chemotherapy remains to be determined.

In breast cancer treatment, a key prognostic determinant for the use of adjunctive therapies and their results is the status of the axillary lymph nodes at the time of primary therapy. A satisfactory dissection of the axillary nodes and histopathologic evaluation is essential for accurate staging.

With these precepts underlying their discussions, the panel addressed the questions in its charge and came to the following consensus.

I. Have clinical trials established the efficacy of adjuvant chemotherapy of breast cancer?

Despite positive and encouraging findings from clinical trials, the answer to this question must be qualified at this time. The value of adjuvant chemotherapy, in terms of demonstrated increase in survival of treated patients, has been established with any degree of certainty only for a select group of breast cancer patients.

Pre-menopausal patients with histologic evidence of lymph nodal metastases who have undergone local therapy by mastectomy have experienced an increase in disease-free and overall survival after adjuvant chemotherapy with established combination regimens. Adjuvant chemotherapy now appears indicated for this defined subset of breast cancer patients.

Since the optimal adjuvant therapy for the pre-menopausal patient with lymph nodal mestastases has not yet been developed, continued clinical investigations are indicated. If entry into a well-planned clinical trial is not feasible or acceptable to patients in this specific group, adjuvant combination therapy is indicated. Regimens which have proven efficacious in recognized chinical trials should be selected. It is the responsibility of the treating physician to evaluate the results of these trials for efficacy and toxicity.

Adjuvant combination chemotherapy, with agents shown to be active in the treatment of advanced breast cancer, has been shown to be more effective than chemotherapy with a single agent. Current information suggests that these drugs should be given at full dosage and for prescribed durations, since lesser amounts of chemotherapy or changes in schedule have shown inferior results.

In combination with adjuvant chemotherapy of Stage II disease, adjuvant radiotherapy has not provided significant increases in survival, although it has reduced chest wall and regional lymph node recurrence in some studies.

II. Do the benefits of adjuvant chemotherapy clearly outweigh the risks?

Various forms of early toxicity have been documented in regimens that have proven to be therapeutically effective. Late effects of the various drug programs have not been identified fully. The survival benefits in pre-menopausal patients with histologic evidence of lymph node metastases (Stage II) appear to outweigh the disadvantages of early toxicity.

Psychological and socioeconomic problems resulting from adjuvant chemotherapy have been identified as risks, in addition to the direct toxic effects of drugs, but they have not been quantitatively defined. In the meantime, education, counseling and emotional support of the patient by the cancer treatment team are of utmost importance. Increased financial burden to the patient, interruptions in family life and occupation, and changes in image may accompany the use of chemotherapy. This panel believes that these problems should be investigated prospectively and addressed directly in future conferences.

III. Should future adjuvant studies include hormonal manipulations?

Studies of hormonal manipulation as adjuvant therapy for breast cancer have shown suggestive benefits, but are not definitive when judged in terms of survival. Current studies on estrogen receptor status are yielding more reliable data on the value of hormonal manipulation in the adjuvant setting. The problems that exist in the assessment of these current data include determination of the relative roles of hormonal and chemotherapeutic treatments, significance of the hormonal effects of the chemotherapeutic agents and reliability of the receptor assays in individual patients.

For now, it appears that no hormonal manipulation has been established with enough confidence to make hormonal alterations—either alone or with chemotherapy—a standard form of adjuvant therapy. Recent data regarding potential benefits for hormonal treatment in patients demonstrating significant estrogen receptor activity are encouraging.

ER activity should be quantified routinely in all patients with breast cancer. In all adjuvant trials, particularly those involving the use of hormonal treatment, ER activity is an essential factor for the classification of patients in planning the design of the clinical trial.

IV. What is the role of adjuvant chemotherapy in Stage I patients?

Patients with histopathologically negative axillary lymph nodes have a good prognosis after appropriate local therapy. The 5-year disease-free survival without adjuvant chemotherapy can be expected to be at least 80 percent. The use of adjuvant chemotherapy in Stage I patients exposes all to risks of toxicity without possible benefit to the majority. Some relevant studies are underway, but no conclusive data from clinical research exist to support the routine use of adjuvant chemotherapy in this situation. Clinical research is now in progress to determine whether it is possible to identify a subset of patients with negative axillary nodes who are at high risk of relapse after primary therapy.

V. What is the role of adjuvant chemotherapy in post-menopausal patients?

Recent analyses of some ongoing adjuvant chemotherapy studies seem to show early benefit in disease-free survival in one or more subsets of post-menopausal patients with positive axillary nodes. The preliminary nature of this information precludes a definitive statement as to the role of such treatment. Clinical investigations should continue to explore the role of adjuvant chemotherapy in post-menopausal women with positive axillary nodes. Broad acceptance of the results of such trials would require concurrent controls, receiving only surgical treatment. Post-menopausal women with ER-positive tumors may benefit from the adjuvant administration of relatively non-toxic hormonal treatment in combination with cytotoxic drugs. It appears logical that hormonal therapy and chemotherapy should continue to be explored in ER-positive post-menopausal women, but only within the setting of well-controlled clinical trials.

Current information indicates that it might be necessary to give multiple drug regimens at full dose to achieve clinical benefit. Retrospective evaluation of patients in one large trial now seems to show survival benefit for those post-menopausal patients who ultimately receive the maximum prescribed dosage in contrast to those who received lower dosage.

Adjuvant chemotherapy of breast cancer is a rapidly changing and progressing field. New concepts have emerged from large, complex clinical trials. But women with breast cancer and physicians need to understand that definitive answers do not exist for the best management of all aspects of this complex disease. The optimal approach to decision-making and treatment is multidisciplinary, within the framework of knowledge provided by current research. Because these drugs are toxic, administration of chemotherapy should be undertaken only by or under the supervision of a physician experienced in their use. Optimal care requires frank and open communication between the physician and patient about the options available and the variables which make up the patient's potential prognosis, both for the risk of relapse and for response to therapy.

Members of the Consensus Development Panel: Stephen K. Carter, M.D. (Panel Chairman), Northern California Cancer Program, Palo Alto, California; George P. Canellos, M.D., Sidney Farber Cancer Institute, Boston, Massachusetts; Barbara E.F. Chambers, Consumer Representative, Washington, D.C.; Sidney J. Cutler, Sc.D., Georgetown University, Washington, D.C.; Edwin R. Fisher, M.D., University of Pittsburgh, Pittsburgh, Pennsylvania; Robert W. Frelick, M.D., Association of Community Cancer Centers, Bethesda, Maryland; Walter Lawrence, Jr., M.D., Chairman, Commission on Cancer, American College of Surgeons; Theodore L. Phillips, M.D., University of California Medical Center, San Francisco, California; Hiram C. Polk, Jr., M.D., University of Louisville, Health Sciences Center, Louisville, Kentucky; Connie Henke Yarbo, R.N., Oncology Nursing Society, Columbia, Missouri.

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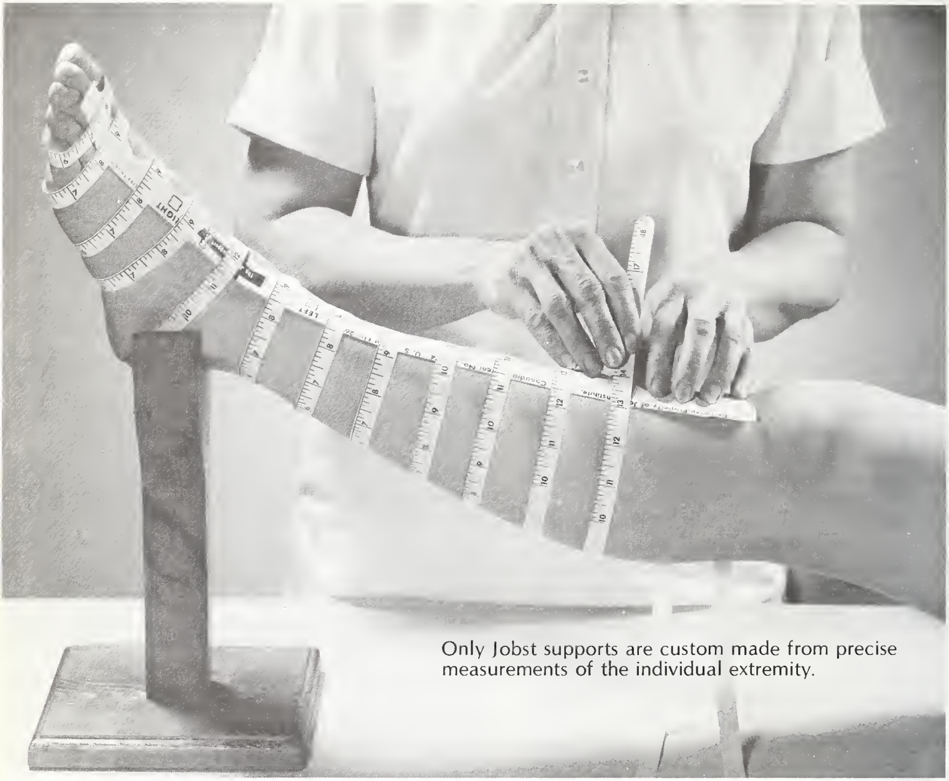

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Connecticut Medical Examining Board and New Legislation—P.A. 80-484

LAWRENCE K. PICKETT, M.D.

The task of the Connecticut Medical Examining Board, in addressing the problem of the incompetent physician for purposes of detection, investigation, and rehabilitation has been drastically impaired by recent legislation. Public Law 80-484 was enacted in the closing minutes of the Legislature and put serious constraints on the functions of all Boards and Commissions and affects the Connecticut Medical Examining Board in a drastic fashion.

Historically the Connecticut Medical Examining Board was expanded by four individuals for the purposes of detecting, treating, and dealing with the incompetent physician, or sick physician, as was noted in the Legislature of those days. In 1976, under Public Law 76-276, four individuals were added to the Medical Examining Board, then numbering five, i.e., one representative from the University of Connecticut at Farmington, an individual who is Chief of Staff of a general care hospital, and two non-physician members, including a lawyer. When these individuals were added, and the Board began to function, nine in number, it was evident there were enough personnel and support to begin to deal with the incompetent physician problem.

Legislation known as "an act concerning disability of physicians—76-276" added the peer review mechanism and the protection of the individuals in the county and state medical societies who would be called upon to do a peer review when complaints were entertained by the Medical Examining Board concerning the behavior, function, or other matters related to the practice of physicians in the state. There was a close cooperation that developed between the investigative staff of the State Department of Health and the Medical Examining Board, giving the opportunity to begin a more sophisticated treatment of the incompetent physician, with protection of the public, rehabilitation of the physician, and protection of the physicians of the State against witch-hunts and other practices which have pervaded other attempts to deal with this delicate problem. Conversations had begun with the State Medical Society Committee on the Impaired Physician. Progress was being made towards a more sophisticated process for this necessary task.

Public Act 77-614, An Act Concerning the Reorganization of the Executive Branch of State Government, the Bureau of Quality Assurance was finalized and the investigative forces of the Department of Health Services were brought into play. The Connecticut Medical Examining Board worked closely with the Department of Health Services and the Bureau of Quality Assurance to develop a system whereby the complaints lodged with the Department of Health Services were reviewed by a physician member of the Board. The Board was assured of and had cooperation with the Commissioner of Health and his department, again protecting the physicians against unwarranted complaints, but directing the investigating process so that all the information available could be obtained for a fair treatment and hearing process, when necessary, before the remainder of the Examining Board. This partnership between the Department of Health Services and the Medical Examining Board continued throughout the year in 1979, resulting in the suspension or revocation of licenses of six physicians, an extensive program of rehabilitation for several, many hearings and many deterrents to other physicians behaving in an unprofessional manner. Again, conversations continued between the Committee for the Impaired Physician of the State Medical Society, with the hope we could begin to introduce legislation that would be more effective in the treatment of physician impairment and further protection of the public interests. Anxiety

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engendered over the State Government reorganization never came to pass. The working arrangement between the Bureau of Quality Assurance, under the direction of Mr. Stephen Harriman, and the Medical Examining Board became one of increasing cooperation, with the addition of an attorney for the Examining Board and for the investigative process, with professional support from Dr. Gary DeWitt in the matter of conducting examinations and in setting the standards for the examinations. Ideal function of the Examining Board was still not achieved because of shortages of staff and budget cuts, reflecting the austerity necessary in the State governmental structure.

The Sunset Legislation ordered that all Boards and Commissions be discontinued as of July 1980, and the Sunset Commission began the reestablishment and the study to give a format for reestablishing those necessary boards and commissions during the entire year of 1979-80. The Medical Examining Board had considerable input to the staff of the Commission. The Examining Board appeared before the public hearings of the Public Health Safety Committee and the Government and Administrative Committee of the Legislature. Several modifications were made in the Sunset legislation to recreate the Medical Examining Board, pursuant to the testimony given by the Medical Examining Board in the public hearings. We were able to incorporate into several versions of the law the assurance of immunity for peer review secondary to another legislative act, i.e., close cooperation between the State Medical Society and the State Medical Examining Board in furthering our attempts to deal with the incompetent physician, using a peer review mechanism to intercede before action was necessary by the Examining Board. Because of the complexity of the problem, the Senate took the suggested bill as it came to the floor and voted to defer action for one year while some of the intricacies of the bill could be understood by the legislators and the legislation could be refined to be more effective in dealing with all boards and commissions, and hopefully, particularly with the Connecticut Medical Examining Board and the impaired physician problem. Unfortunately, the Assembly did not agree with the Senate and the matter was referred to a Conference Committee. This was late in the legislative calendar and indeed a conference bill was agreed upon minutes before close of the Legislature. Time prevented dissemination of the final form of the bill before passage and certainly without any input from the Connecticut Medical Examining Board or the Connecticut State Medical Society in molding the nature of the new legislation. As the result, Public Law 80-484 was enacted. Massive changes have taken place.

The principal changes brought about by P.A. 484 are the removal of the investigative process and the process for processing complaints from the Department of Health Services, putting them in the hands of the Board. The combining of the Boards of Medicine, Osteopathy and Homeopathy, a fiscally sound and agreed-upon move, was abandoned. The legislation stipulated that there be established a panel of not less than two, and no more than four, practitioners of the profession to serve as an adjudications panel. Complaints will be received and investigated by such a body composed of two practitioners and a representative of the Department of Health Services. On conclusion of the investigation, the panel will inform the Board or Commission, who shall then determine what disciplinary action should be taken. The Board or Commission should file a monthly report with the Department of Health Services to show the disposition of all complaints the preceding month. During the calendar year 1978 the Board received 215 written complaints and many verbal and other complaints. If all these complaints are to be directed to members of the Examining Board, there will be a considerable increase in the amount of time to be devoted and difficulty with communication with Examining Board members all over the state and the State Health Department where the complaints will be received. Obviously, with adequate staff support from the Department of Health Services, this could be carried out. Such support has not been evident in the current budget of the Department of Health Services.

In addition to these tasks, i.e., the receipt and dealing with investigations and complaints, the keeping of the minutes, should the panel evaluating the complaints determine that there has been a violation of the statutes, the panel must hold a compliance conference in accordance with Section 4-182 (c) of the Connecticut General Statutes. If the panel continues to perceive a violation of the statutes, they must make formal charges, develop testimony and witnesses and present its case to the Board. The Board would then adjudicate the formal charges, write a memorandum of decision and order to reflect such adjudication. Obviously, this is a very time-consuming and very necessary function which has been carried out to date with the active staff support of the Department of Health Services, but is now relegated to the Board of Medical Examiners without any demonstrable increase in the staff support or the personnel to carry out this function. All of the above is superimposed upon the very critical inclusion in the statute which indicates that members shall not be compensated for their services, but shall be reimbursed for necessary expenses incurred in the performance of their duties.

Prior to this time there has been a very modest per diem which indeed in a very small way reimbursed the practitioners for leaving their practice and spending an inordinate amount of time in hearings and board deliberations. With the per diem removed, as the Statute indicates, a great deal more time and effort are expected of the members of the Board.

The Medical Examining Board has met, considered all the aspects of the Statute and will continue to function to the best of its ability under the severe constraints. Support has been offered to the extent possible from Mr. Stephen Harriman of the Division of Quality Assurance, Mr. William Edwards assigned by the Department of Health Services as a single staff man who functions as a hearing officer, overseeing the hearing and investigations of the Board; and as previously mentioned, the examining function of the Board will be assisted by Mr. Gary DeWitt. The Board has been most satisfied with the support of the Department of Health Services as it has been functioning over the past years, and it is hopeful that sufficient personnel and resources can be made available so that the increased burden will not impact negatively on the function of the Board. Vigorous attempts must be made, beginning immediately, to formulate corrective legislation for the next legislative session so that sufficient responsibility can be delegated by statute to the Connecticut State Medical Society and its County counterparts for peer review mechanisms, for the opportunity for rehabilitation, monitoring and disciplinary action for physicians who have gone astray. Currently, by statute, all of these functions seem to rest with the nine members, six professional and three lay members, of the Connecticut Medical Examining Board. The practical problem of addressing and dealing adequately increasing numbers of complaints and problems approaches the ridiculous. The public interest and safety and the responsibilities of the medical profession are not going to be adequately fulfilled.

Section 15—Public Act 80-484

Reasons for Revocation of Physician License

Sec. 15. Section 20-13c of the general statutes is repealed and the following is substituted in lieu thereof:

The board is authorized to restrict, suspend or revoke the [certificate of registration] LICENSE or limit the right to practice of a physician IN ACCORDANCE WITH SECTION 137 OF THIS ACT, when the board finds that such physician is unable to practice medicine with reasonable skill or safety for any of the following reasons: (1) Physical illness or loss of motor skill, including but not limited to deterioration through the aging process; (2) emotional disorder or mental illness; (3) abuse or excessive use of drugs, including alcohol, narcotics or chemicals; (4) illegal, incompetent or negligent conduct in the practice of medicine; (5) possession, use, prescription for use, or distribution of controlled substances or legend drugs, except for therapeutic or other medically proper purposes; (6) misrepresentation or concealment of a material fact in the obtaining or reinstatement of a certificate or license to practice medicine; [(7) advertising in relation to the practice of medicine which is intended or likely to deceive the public;] or [(8)] (7) violation of any provision of this chapter or any regulation established hereunder.

**Bracketed items are deletions of previous language of the law; capitalized and underlined items are additions to previous language.*

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Multimillion-Dollar Verdict in Malpractice Case in Connecticut: A Complex Trial Record

WILLIAM J. CURRAN, J.D., LL.M., S.M. HYG.

New England has not been an area where very large verdicts have been common in medical malpractice cases. Widespread publicity was therefore to be expected when the Supreme Court of Connecticut recently upheld as proper and justified a jury verdict of $3.6 million.[1]

The defendant was a local general hospital with a psychiatric ward in which a 23-year-old psychotic patient harmed herself severely in a seclusion room, having been unattended for nearly four hours. The jury had not found negligence against the plaintiff's psychiatrist but returned its verdict only against the hospital. The defendant claimed that the verdict was obviously excessive, being four times as large as any ever returned in the state, and that "its size alone [was] indicative of prejudice, passion, bias, sympathy and total misunderstanding of the law and the facts on the part of the jury."

The trial judge had not only denied a motion to set aside the verdict as excessive but had also remarked that the evidence would have supported "a substantially higher verdict."

The trial judge's comments were certainly unusual in the relatively conservative judicial precincts of Connecticut. Most general discussion of the case will tend to note only the size of the verdict, not the circumstances of the case. As the entire, complex trial record is examined, however, the full picture of an aggravated, tragic situation is revealed. The features leading to a verdict so high can be summarized as follows: negligent failure to safeguard a very sick patient; a blatant effort by the hospital to rewrite, alter, and disguise the patient's record; serious neurologic injury and disability with conscious pain and suffering; and the requirement for lifelong medical and nursing care for a young plaintiff with a life expectancy of 41 years after the trial. Although it may not be part of the legal precedent for which the case will later be cited, one could also note the high technical quality of the plaintiff's expert witnesses in both medical and economic areas, the use of a 20-minute videotaped motion picture starkly displaying the plaintiff's condition and requirements for daily nursing care (the plaintiff could not testify personally because of her conditon), and the professional competence of her counsel in preparing and presenting the case at trial.

The plaintiff had been admitted on January 14, 1976, in an agitated, confused condition diagnosed as schizophrenia. She was later placed in seclusion, and a steel-frame bed and other furniture were removed for the sake of safety. After three days, the bed was returned to the room without authorization from the plaintiff's psychiatrist. During the hospital stay, restraints were often necessary. On January 21, the doctor ordered "antipsychotic medication," but the nursing staff failed to record the order until the following day. At that time, the hospital pharmacy had run out of the medication. The doctor was not notified and the patient was not given antipsychotic medication over the next few days; her condition worsened and she spoke of voices telling her "to hurt herself." On the morning of January 24, the patient was observed to be awake between 7:30 and 8:00 a.m. No one on the nursing staff spoke with her. No one entered the locked room from 6:15 a.m. until slightly after 10:00 a.m., when she was discovered with her head wedged between the steel side rails of the bed as she was kneeling on the floor. She was then unconscious with no pulse or respiration. The patient was revived but had permanent brain damage. At the time of the trial she was in a semicomatose condition and cared for in a skilled-nursing facility.

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The hospital attempted to characterize the failures of observation and supervision as merely poor professional judgment. It was also argued that the bizarre manner of self-destruction used by the psychotic patient was unforeseeable by the nursing staff and could not have been prevented. The Supreme Court had little trouble dismissing both defenses. "Poor judgment" was held not a defense if it was proved to be professional negligence. One of the plaintiff's expert medical witnesses described the conduct of the staff as "not a question of judgment but rather a sheer matter of responsibility." On the issue of foreseeability, the court pointed out that the hospital needed only to anticipate and guard against the general type of injury, i.e., self-imposed harm within the seclusion room. There was no necessity to foresee the exact action taken. Two classic papers on the law of foreseeability published a quarter of a century earlier were cited as controlling on the issues.[2,3] Ironically, one was written by a law professor at a nearby Connecticut law school—Fleming James of Yale. (As a former tort-law teacher who used these papers as sacred gospel in instructing first-year law students, I was pleased with these relevant citations by Justice Parskey.)

The court pointed out that the amount of a verdict is particularly within the province of the trier of fact and will not be disturbed unless plainly exorbitant. Justice Parskey summarized the evidence of the injuries and the need for lifelong medical and nursing care. Up to the date of the trial, the medical and hospital bills were $317,000. Annual future bills were estimated by plaintiff's witness at $91,900. The chairperson of the Department of Economics at the University of Hartford testified and projected the cost of professional care over the plaintiff's expected life, discounted for present value, as in excess of $6 million. Another witness estimated the plaintiff's loss of earning capacity, also discounted to present value, as $220,000. To these figures the jury could add general damages for the plaintiff's conscious pain and suffering. The defendant's counsel did not offer contradictory evidence on these factors.

It may be judged, after a review of the above evidence and circumstances, that a large verdict was supported in this instance. For the future, however, the key may be that the barrier against a large multimillion-dollar award was breached. Although the first big cases, the pioneer findings, continued to be uncommon in later years, they became the grist for the insurance-company underwriters and their always pessimistic predictions; the malpractice premiums will now take another quantum leap upward. The so-called reforms of the mid-1970's in malpractice law, including arbitrary limits on awards for damages, have not fared well under challenges based on constitutional law, as predicted at that time in this column.[4] The answer will probably be found more readily in improved patient care and well-planned risk management and claims processing than in poorly developed legal reforms.

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Second Opinions Verify Surgery

A new study says the "belief that millions of people in the United States are talked into unnecessary surgery by their doctors apparently is unfounded." A survey of 1,591 patients in the Massachusetts Medicaid program, which mandates second opinions for elective surgery, found that "only 11% were told they did not need the operation when they asked for a second opinion," and where a third opinion was sought, "the doctor sided with the initial recommendation 70% of the time." The study by a group of Boston doctors, published in the *New England Journal of Medicine,* "contradicts a 1974 report that found more than 30% of those who voluntarily sought a second opinion were told they didn't need the surgery."

—AMA *Legislative Roundup,* June 13, 1980

AMA Missions for the '80s

A REPORT TO AMERICA'S PHYSICIANS ON THE GOALS AND FINANCIAL CONDITION OF THE AMERICAN MEDICAL ASSOCIATION

Mission 1: Scientific Policy and Information
Mission 2: Socioeconomic Policy and Information
Mission 3: Assure Quality of Medical Care
Mission 4: Represent the Medical Profession
Mission 5: Strengthen Organized Medicine
Mission 6: The AMA as an Organization

AMA Mission 1

Scientific Policy and Information

The Scientific Policy and Information area is the foundation of the Association's information products. It buttresses the two goals of the AMA—the advancement of the art and science of medicine and the enhancement of public health.

Special emphasis is placed on the development and promotion of policy statements on current and emerging scientific issues. This requires detailed knowledge of the issues by both the Council on Scientific Affairs and its staff.

AMA Journals are integral to this mission, disseminating scientific information to the profession. As the largest publisher of medical information in the world, the Association provides physicians with a forum for the expression of its views on all aspects of medicine. Furthermore, the appeal of the various journals has been broadened recently by increasing the amount of material relating to a variety of practice situations.

Publishing Scientific Information

Symbolizing the diversity of work accomplished in support of this Mission are three 1979 activities. A report was prepared by the Council on Scientific Affairs on aorto-coronary by-pass graft surgery which presented guideliness for the selection of candidates for this procedure. Readership of the *Journal of the American Medical Association (JAMA)* was extended to 11 countries which clearly established the AMA as the principal publisher in the world of medical information. And a series of books is being readied for publication beginning in 1980 to bring medical information to the public.

The Council on Scientific Affairs

When the Board of Trustees issues a policy statement on a scientific question, it has been debated on the basis of a report especially written by the Council on Scientific Affairs. In 1979, the Council, in addition to its report on aorto-coronary by-pass surgery, prepared major statements on such topics as concepts of nutrition and health, the care of the chronically mentally ill, guidelines for the treatment of hypoglycemia in the maturity onset-type diabetic and 13 other major statements. The Council has also assembled a group of consultants to advise it on the AMA's position on the risks of nuclear power, indications for fetal monitoring and other similar questions.

One Message—Two Audiences

The science of medicine has two principal audiences, the public and the profession. Each has its own channels of communications.

Communicating with the Public

Press releases that highlight the news contained in *JAMA* and carefully written in lay language, are distributed to nearly 800 newspapers on a weekly basis.

Radio manuscripts that feature "health tips" are sent to 1,500 radio stations for incorporation into their broadcasting schedule. Over the years these stations have indicated in AMA surveys a consistently high level of usage.

Television public-service announcements, 30-second filmed spots which compete effectively with paid commercial messages, are produced on a variety of health-related topics such as: the need for immunization, getting proper exercise and proper nutrition.

Printed pamphlets that answer individual requests for health education information are distributed to the public in extraordinary numbers. In 1979, 350,000 copies of 90 AMA-prepared pamphlets were distributed on such diverse topics as first aid, skin care, blood pressure, physical fitness and "athletics for the diabetic." Another 50,000 answers were prepared on specific health education questions from the public.

Books on health care topics intended for consumers will soon be published. Written by professional authors, under the direction of AMA staff and medical consultants, the books will be published by Random House. The first book, a first-aid handbook and emergency care manual, will be issued in the Fall of 1980.

Communicating with the Profession

The AMA's nine specialty journals, *JAMA, American Medical News* and its *Impact,* a magazine format insert, continue to make the Association the principal publisher of scientific information in the world. A major event in scientific publishing in 1979 was the expansion of *JAMA's* readership into 11 countries. The publication is now printed in Spanish, Portuguese, French and Japanese. Circulation of *JAMA,* including the 225,000 distributed outside of the United States, is now 500,000 monthly, bringing the total to 13,800,500 copies distributed yearly. And the total for all AMA periodicals is more than 32,000,000 copies distributed yearly.

The fourth edition of the *AMA Drug Evaluation* book was published in 1979. The book assesses the efficacy of more than 1,500 drugs and makes distinctions between preferred modes of treatment and less satisfactory drugs. Each drug was evaluated by a panel of 300 distinguished physicians, under the auspices of the Council on Scientific Affairs.

Conferences that concentrate on special interests remain an essential form of professional communication. For example, in 1979 the Association held three conferences on Foods and Nutrition. Another conference discussed rural health, yet another was concerned with environmental and occupational health. And in cooperation with the Federal Aviation Authority, a special conference was held on neurological conditions associated with aviation safety.

A TV satellite extended the reach of medical communications in 1979. For example, in association with the American Dietetic Association, a continuing medical education program was transmitted to audiences in 550 hospitals.

Nutritional reference works were published in 1979, including a book on *Sodium and Potassium in Foods and Drugs* and a statement on "Guidelines for Essential Trace Element Preparations for Parenteral Use," which appeared in *JAMA.* A statement entitled "American Medical Association Concepts of Nutrition and Health" was adopted by the House of Delegates in July, 1979, and published in *JAMA.*

The AMA library provided responses to nearly 48,000 requests from physicians on scientific and socioeconomic topics. It initiated over 8,000 computer searches of the world medical literature for scientific information and served the public with responses to nearly 27,000 telephone calls.

AMA Mission 2
Socioeconomic Policy and Information

The heart of this mission is the provision of policy support on issues related to medical practice, dissemination of information to the profession and the public on the delivery of health care, and support for AMA legislative activities. The cost of health care, and its control, has assumed an increasing share of attention in this mission.

The AMA is working to provide greater consultation to physicians, medical societies and others on a wide variety of topics. These relate to various aspects of medicine and its practice modes including solo practice, group practice, specialties and physicians practicing in hospitals.

How medicine is practiced, how it's financed, the systems it develops for practice, how it uses modern business techniques, and how it relates to other allied health-oriented professions are all in a continuing state of change. Preparing the profession for understanding and dealing with these changes is an important aspect of this mission. As we look to the future, the goals of this mission will continue to serve the member in ways directly related to his or her practice and improve the delivery of health care.

Slowing Cost Escalation

The AMA's actions last year—and the year before that—contributed to the fact that health care was the only major area of the economy to decelerate its rate of increased costs voluntarily. In the same period, physicians demonstrated their leadership in the fight against inflation by holding the increase of their fees nearly three points below the Consumer Price Index.

In 1979, health care costs, as measured by the Consumer Price Index (CPI), were held to an increase of 10.1 percent over the preceding year, compared to a 13.3 percent rise in the cost of the "All Items" segment of the CPI. This is the record of a profession voluntarily working to restrain costs in the face of:

A national economy fighting double-digit inflation.

A sophisticated technology continuing to expand.

A nation of consumers expecting continued quality care.

The effects of these pressures have been slowed through the Voluntary Effort (VE) to contain health care costs, a coalition of physicians, insurers, hospital leaders, manufacturers, local government, business, consumers and labor. It is estimated that voluntary programs saved the American public $3 billion on its total health care bill over a two-year period.

For 1980, the VE Steering Committee established some important goals in the ongoing effort to contain costs. Targets include continuing the deceleration in total inpatient community hospital expenditures, physician fees and total number of hospital beds.

The AMA-sponsored National Commission on the Cost of Medical Care, after 18 months of work in 1976-77, made 48 recommendations on what the nation as a whole should do to control costs in the health care system. The ten-year agenda is continually being implemented through actions accepted by the AMA House of Delegates.

Health Care Delivery

The delivery of physicians' services and techniques of quality assurance programs command a large share of AMA efforts. For example, in 1979, detailed studies were prepared on the subjects of health planning, health maintenance organizations (HMO) and Professional Standards Review Organizations (PSRO). Under contract to the former Department of Health, Education and Welfare (now Health and Human Services), the AMA also completed a project to develop sample sets of criteria to assist PSROs in their review efforts on the medical necessity and appropriateness of surgical procedures.

Approximately 9,000 physicians have been placed in medically underserved areas over the past several years through a physician placement service. There are currently 5,000 openings for physicians on file.

A system standardizing codes used by physicians in billing third-party payers has been devised. The system, called Current Procedural Terminology (CPT), is a comprehensive five-digit coding system for medical procedures. The fourth edition of the book detailing the system was published in 1979. CPT is now being proposed for adoption by the federal government for use in the Medicare and Medicaid programs.

Practice management seminars, which are concerned with the business side of a medical practice, are attracting an increasing number of physicians. The seminars are designed for the physician just setting up practice, for the seasoned physician and for the physician looking to retirement. In 1979, nine different seminars, which in the aggregate totaled 248 days, were attended by nearly 9,000 physicians.

The jail health care project, which was funded in part by the Law Enforcement Assistance Administration of the U.S. Justice Department, has received wide-spread recognition. The program's guidelines, developed by a broadly based committee, are implemented by state medical societies. To date, 22 states and Puerto Rico are currently working to improve the health care facilities of 225 jails. Another 145 jails work with the jail program on an informal basis. A total of 59 jails have been accredited by the AMA as providing an acceptable level of care to their inmates.

The provision of replacement physicians for vacationing officers in the National Health Services Corps and the Indian Health Service is the work of Project USA. This service is under contract with the Federal government, and in the seven years of its existence has placed 9,000 physicians.

AMA Mission 3
Assure Quality of Medical Care

The monitoring of the career-long education of the American physician, from medical school to graduate training, and through continuing medical education, is the purpose of this mission.

In 1979, as a matter of increased priority, the AMA resumed accreditation of continuing medical education and the many responsibilities which that implies. Additionally, policy development in medical education and graduate medical education is covered in this AMA mission. The AMA continues with others to work with the Coordinating Council on Medical Education as a partner in major medical education policy development.

Career-Long Education

In 1962, the AMA initiated the accreditation of continuing medical education to improve its quality and availability and to assist physicians in their choice of appropriate continuing education.

At the 1979 Annual Meeting, after two years of sharing this responsibility of accreditation with six other organizations in the Liaison Committee on Continuing Medical Education (LCCME), the AMA resumed the accreditation of CME. The AMA Council on Medical Education and the Board of Trustees established the Committee on Accreditation of Continuing Medical Education (CACME), after seeking nominations from all components of the Federation, from specialty boards, the American Hospital Association, Federation of State Medical Boards and the National Medical Association. CACME policies are determined by the AMA House of Delegates.

The Committee works under the supervision of the AMA Council on Medical Education and is responsible for and responsive to the needs of physicians and local medical societies.

In 1979, a major commitment was made to the production of video tape home study courses in continuing medical education (CME) called "Video Clinics." Accompanied by study guides, five programs were made available in 1979, five more Video Clinics will be completed by mid-1980; a total of 40 are projected over the next three years.

The AMA, in 1979, also sponsored 15 regional CME meetings offering 2,500 hours of courses, plus a national Winter Scientific Meeting. In 1980, the number of regional meetings will be reduced to ten, but the number of course hours offered will remain the same.

Monitoring Medical Education

An activity which receives only passing public recognition, but which helps give meaning to the AMA's stated purpose, to advance American medicine, is the Association's work with organizations in monitoring the nation's medical education system.

Medical schools, their curricula and their facilities, are accredited by the Liaison Committee on Medical Education (LCME). This committee is composed of six representatives from the AMA, six from the Association of American Medical Colleges (AAMC), two public members, two students, one Federal member, and one Canadian representative. In 1979, 43 existing schools were surveyed and accredited and two new schools were accredited.

Graduate medical education is monitored and accredited by the Liaison Committee on Graduate Medical Education (LCGME), a committee of the AMA, American Hospital Association, AAMC, Council of Medical Specialty Societies and the American Board of Medical Specialties. Last year more than 1,212 residency programs were reviewed by the residency review committees in which the AMA participates with each appropriate specialty board and, in some cases, with the professional society as well.

AMA Mission 4
Represent the Medical Profession

The goal of this mission is to bring before all levels of government, the public and the whole of the health care field, the views of American medicine. The mission involves direct legislative activity at both the federal and state level and deals with the executive and judicial level of government as well. This mission is also responsible for the dissemination of scientific information to the profession and the public.

Matters of increased priority in this mission are public relations, media relations, and closer communications with all levels of organized medicine.

New emphasis on state legislative affairs is a current priority of this mission in order to encourage greater participation by state, county and specialty societies in the development of draft legislation.

The AMA in Court

As a national medical association with the stated purpose of improving health care delivery, it is the AMA's responsibility to challenge in court those actions—both governmental and private—which are not in the best interests of the nation's physicians and their patients. For that reason, and because the AMA is at the leading edge of organized medicine, it is involved frequently in litigation either as plaintiff or defendant.

The AMA achieved two victories in the courts in 1979:

- A lawsuit filed in 1978 by the AMA and the American Optometric Association, in which the U.S. Court of Appeals in Washington, D.C., in agreement with the Association sent back to the Federal Trade Commission (FTC) its proposed rule to prohibit states and professional associations from restricting the advertising of ophthalmologic goods and services. The court suggested that the FTC may have infringed on the rights reserved for states.
- A Florida District Court issued a permanent injunction in the Fall of 1979, to prevent the Secretary of the former Department of Health, Education and Welfare from publishing the names of physicians who had received Medicare and Medicaid payments, with the amounts they had received. The AMA opposed the release of these names on the grounds that the information gave an inaccurate picture of a physician's practice and income with no reference to costs. The motion for an injunction was initiated by the Florida Medical Society and joined by the AMA on June 12, 1978. The government is appealing the decision to the U.S. Court of Appeals for the Fifth Circuit Court.

Two questions, physician advertising and the chiropractor-physician relationship, are currently under litigation:

- The AMA's judicial appeal of an FTC order, issued in the Fall of 1979, which limits the Association's right to involve itself in physician advertising practices and the contract arrangements of physicians, will probably be heard in the Spring. The FTC accused the AMA of prohibiting physician advertising. The AMA argues that it has not prohibited the advertising of such verifiable facts as office hours, specialty, training or fees. It has, however, discouraged the solicitation of patients through testimonials or misleading, deceptive or fraudulent statements.

The appeal is based on questions of the FTC's jurisdiction over non-profit organizations and the violation of the AMA's First Amendment Rights. The Association's brief makes the point that the interpretations of the AMA "Principles of Medical Ethics" which are at the heart of the FTC order, were under revision when the agency filed its complaint. The FTC order, although it recognizes the AMA's "unique and valuable" role in enforcing reasonable, ethical guidelines for physician advertising, places unacceptable restrictions on the Association's right to involve itself in the establishment of guidelines for advertising or protecting the public from improper fees.

- The issue of the physician-chiropractor relationship is at the heart of the FTC suits which have been brought by chiropractors or their associations. To date, of the five suits brought against the AMA by—or on behalf of—the chiropractors, only the case in Pennsylvania has been brought to partial settlement. On May 16, 1979, the AMA joined with six of the co-defendants in the settlement that reaffirmed that each individual physician may decide whether to accept a patient referred by a chiropractor or another limited, licensed practitioner.

In the New York suit, the Federal District Court judge dismissed the charge that the AMA and 13 other defendants violated New York antitrust laws, ruling that they do not apply to the medical profession. Charges that the defendants violated Federal laws are still before the court. Three suits, in Illinois, New Jersey and Iowa, are still in process.

AMA and the National State Legislatures

The posture of the AMA in the courts—positive, responsible, tenacious—is true of the Association's presence in Congress as well.

A total of 141 statements which commented on proposed laws or regulations, the overwhelming majority of which were positive in tone, were submitted to Congressional committees, sub-committees or regulatory agencies in 1979 alone. Some of these statements were made in person, by officers or trustees, while others were delivered in the form of written testimony. In addition, the AMA prepared 26 draft bills for introduction on as many topics. This on-going activity reinforces the AMA's national presence and establishes a platform to influence legislation vital to the health care of the public in each session of Congress.

For example, the Association acted to:

- Reduce the scope of what the AMA considered to be improper modifications of the Food, Drug and Cosmetic Act and offered amendments believed to improve the Act. The resultant law should speed the approval process of new drugs and medical devices.
- Fight for the confidentiality of patients' records on many fronts, such as computer technology, Professional Standards Review Organizations, Medicare and Medicaid.
- Bring medicine's voice to other subjects addressed by the Congressional Committees and regulatory agencies including maternal and child health care, Keogh Law, saccharin, regulatory reform, foreign medical graduates, clinical laboratory standards, variable incentive pay for federal physicians and national health insurance.

State Legislation and Regulation

State legislation and regulation continues to be an important, developing activity. The AMA has produced model bills which medical societies may, if they choose, introduce in the state legislatures. The Association acts as a resource and advisor to the state medical societies and as a conduit for the exchange of information. The AMA also participates in a number of organizations having significant state legislative interests, such as:

- The National Association of Insurance Commissioners Advisory Committee on Regulatory Issues in Health Care Delivery and Finance.
- The Advisory Board of the National Commission on the Confidentiality of Health Records.

Communicating with the Public

The public relations activity of the Association utilizes several communications channels:

- Open relations with the press and electronic media are maintained through constant contact with media representatives and average 300 such contacts monthly. News releases on socioeconomic affairs are prepared as needed. Material is also prepared for radio and television stations.
- Mailings on an as-needed basis, which give background information on topics of interest to the public, are sent to editorial-page editors. Additionally, feature stories are distributed to newspapers on a variety of subjects, in an effort to get news from the AMA into the well-read feature sections.
- A complete directory of every Doctor of Medicine in the United States, which lists his or her medical credentials and locations.
- Since June, 1978, over 100 leading companies have been visited by AMA leaders to learn their views on health care issues and to make known to the business leaders the recommendations of the National Commission on the Cost of Medical Care. As an off-shoot of the program, pilot projects in cost control have been initiated by the AMA in Birmingham, Alabama; Nashville, Tampa and Denver. Steering committees were appointed in each city consisting of four physicians from the local medical society and four business leaders to guide the project.
- Close liaison is maintained with the public relations departments of the component medical societies.

Inter-Professional Relations

Increasingly, the professional life of a physician involves relationships outside the traditional practice situation with group practices, prepaid health plans, expanded-facility clinics and hospitals. The AMA has provided assistance to physicians in these new relationships through legal interpretation and, on occasion, intercession in cases in which regulations and policy decisions made by hospital management have adversely affected the physician and may be precedent setting.

AMA Mission 5

Strengthen Organized Medicine

Every Association exists to serve its membership. Only by increasing the number of its members can it continue to speak authoritatively. The AMA is no exception to this rule, and so this mission works to design individual programs to spur membership recruitment, in cooperation with state medical societies.

As a new emphasis the AMA is working to target special groups of physicians who might, with a greater understanding of the value of organized medicine, join at all levels. Personal communication and speaking engagements by AMA officers, trustees and key staff help to increase understanding of individual concerns, develop consensus and reach conclusions as to how each level of the federation can be of greatest benefit to the individual physician.

Day-to-day contact with all elements of the federation is a continuing priority for AMA staff. The focus of national resources on the needs of the state, specialty or county society is increasingly required of the AMA.

Membership

The measure of the AMA's vitality is seen in the addition of 12,000 new members in 1979.

Programs to retain current members and attract new ones are on-going activities. The rate of increase in physician dues-paying members last year exceeded the rate of growth of the physician population. Total membership for the year was 223,000. An especially heartening result was the attraction of 20,300 residents and 20,250 medical students. The total for these categories (40,550) was 8,000 above the 1978 figure. To continue the expansion of AMA membership, special membership campaigns will be implemented in a number of states in 1980.

Students and Residents

With the increased participation of students and residents in the AMA, they have also assumed responsibilities in the Federation. Students now have representation on six AMA Councils and most state societies provide membership. The Resident Physicians' Section, in addition to publishing a workbook on cost effective medical care, also sponsored a project to improve the teaching skills of residents.

Foreign Medical Graduates (FMG)

FMG Affairs is an activity which had its beginnings in 1978. This committee provides services to individual FMG groups and consultative services to the AMA Board of Trustees. The focus of the committee to date has been on legislation, examination and licensure, and Americans in foreign medical schools. There is, as well, a program to encourage an even greater FMG participation in the councils and committees of the AMA.

Specialty Societies

In 1978 specialty societies obtained direct representation in the AMA House of Delegates; there are now 57 societies with delegate status. In addition to maintaining on-going liaison with each of the societies, the AMA held ten legislative briefings for the societies. An associated activity is the Interspecialty Advisory Board, with representatives from 54 national specialty societies. This body acts in an advisory capacity to the AMA Board of Trustees.

Communications with Federation

Communication with all medical societies is through regular publications—*American Medical News, AMA Newsletter, Impact, Medical Society Relations Memo* and a wide variety of newsletters including *Legislative Update, Negotiations Update* and others. Regular visits to the meetings of state and local medical societies by Officers and Trustees of the Association and constant liaison by AMA staff with the state and specialty societies is maintained. "Official family briefings" are held on a regional basis for the officers of state medical societies. At these meetings presentations are made on questions of interest to the Federation.

Medical societies are helped to develop impaired physician programs. The AMA works closely with state medical societies, the Resident Physician Section and specialty societies in the development of programs to prevent physician impairment and to promote well-being. AMA model legislation has been prepared that can be used to modify state medical practice acts to provide treatment and rehabilitation of impaired physicians. Many of the principles of the model legislation have already been incorporated in legislation passed by 35 states.

AMA Mission 6
The AMA as an Organization

Various AMA support units provide the management, administration, fiscal control, research, data handling and personnel to support the House of Delegates and its Councils and Committees in their policy development and implementation.

Currently, the priority emphasis of this mission is the building of a progressive business-oriented leadership term. Recruitment of talented management personnel, the continuation of the careful management of AMA finances and managing the tremendous information flow of the Association are all challenges which this mission meets.

Policy-related research is a continuing priority of this mission. Greater public and professional visibility of AMA officers and trustees is also a goal that has increased emphasis.

Analysis of the Health Care System

The AMA is justifiably considered by the profession, the government and the public as the indispensable source of statistical information about medicine. Essential to this bank of information is the AMA's Masterfile on every doctor of medicine in the U.S., the Periodic Survey of Physicians and the Group Practice Census. In addition, the AMA sponsors periodic surveys by Market Opinion Research and the Gallup Organization to assess physician and public attitudes on key issues. Three books are published annually to give wide dissemination to these studies: *Physician Distribution and Medical Licensure in the U.S., Profile of Medical Practice* and *Socioeconomic Issues of Health.* Other studies and results of the opinion surveys are issued as needed.

Information Systems Steering Committee

As the result of a Business System Planning Study which was started in July, 1978, a general design for an information system and data bases was developed. The study also established priorities for the implementation of information systems and recommended the formation of the Information Systems Steering Committee, composed of the senior management of the AMA and chaired by the Deputy Executive Vice President. This committee has the responsibility for setting electronic data processing priorities, and for the review and approval of new systems. The committee also reviews the hardware and "software" plans of the Association. For example, in 1979 the first Computer Facilities Plan for 1979-80 was published. As a result several hardware acquisitions were made to improve the Association's computer capabilities.

Current Medicolegal Issues

THE AMA CITATION

Radiologists Have Duty to Inform Referring MDs of Complications

Radiologists have an affirmative duty to advise referring physicians of complications that might arise from radiological procedures, the Arizona Supreme Court ruled.

A patient who had occlusive arterial disease was under the care of a general surgeon from October 1972 through January 1974. During that time, the patient underwent eight femoral arteriograms. On December 2, 1973, the patient entered a hospital to have another arteriogram, which was ordered by the surgeon. The surgeon feared an impending occlusion of the extracranial vessels of the aortic arch.

Because the patient's groin area had been the site of previous femoral arteriograms, the surgeon urged the radiologist to perform an axillary (armpit) arteriogram. The radiologist agreed, even though he was aware that the patient was taking Coumadin, a chemical that impedes the normal clotting of blood.

The radiologist began the arteriogram, but the guide wire would advance only six inches into the brachial artery. He then inserted a catheter through which there was injected a small amount of dye into the artery. He then determined that the guide wire had lodged in the wall of the artery. The radiologist withdrew the catheter and guide wire, and put manual pressure on the area of the puncture to stop the bleeding. However, a large hematoma formed on the axilla.

The radiologist telephoned the surgeon and told him what happened. The surgeon examined the patient, but decided the hematoma did not require surgery. Two days later the patient had a femoral arteriogram, but no occlusion in the carotid artery was found. The patient was released from the hospital on December 4, 1973.

The patient continued to have pain in his right arm, and on December 27, 1973, the surgeon performed vascular surgery on him. Then, on January 4, 1974, the surgeon and another surgeon operated on the patient to remove scar tissue surrounding the nerves in the axilla area resulting from the hematoma.

The patient filed a malpractice suit against the surgeon, the radiologist and the hospital, alleging negligence resulting in permanent nerve damage and lack of informed consent. All defendants except the radiologist were dismissed from the case prior to trial.

The jury found in favor of the radiologist, and the patient appealed.

The Arizona Supreme Court reversed. The evidence established that the radiologist had an affirmative duty to inform the referring surgeon of the potential dangers of any complication that might result from the procedure undertaken by the radiologist, the court said. It was not solely the referring physician's responsibility to decide how to handle the case once he was advised of the hematoma. The radiologist knew of the potential complication of an axillary arteriogram, but failed to pass this knowledge on to the referring physician. It could reasonably be concluded that the radiologist had acted below the standard of care, the court said.

The radiologist had no duty to inform the patient of the potential complication, however, so long as the patient was under supervised medical attention and did not demand to be fully advised, the court concluded.—*Matson v. Naifeh,* 595 P.2d 38 (Ariz. Sup. Ct., April 19, 1979, rehearing denied, May 22, 1979)

MD Sues Other MD for Alleged Libel

A physician's suit for defamation against a second physician over comments made before an executive committee of a hospital was not barred by the Medical Studies Act, an Illinois appellate court ruled.

The first physician contended that at the committee meeting the second physician (1) expressed his unwillingness to continue to work with the physician because of his dishonest and unethical practices; (2) stated that

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THE CITATION, Vol. 39, No. 11, Sept. 15, 1979. THE CITATION is a newsletter on medicolegal issues prepared by the Office of The General Counsel of the American Medical Association.

the majority of the physicians' colleagues had a very low opinion of the first physician's abilities; (3) advised that he had warned several people of the physician's shoddy practices and that one such practice had prompted his dismissal from another hospital; and (4) cited an example where the first physician's method of delivery had resulted in serious injury to an infant.

In the first physician's complaint against the second physician for compensatory and punitive damages, he claimed that the remarks were made with knowledge of their falsity or with reckless disregard of their truth or falsity. He charged that the second physician neither consulted hospital records or made any investigation to determine the accuracy of the statements. The first physician contended that he had lost patients and was not reappointed to the hospital staff because of the statements. A trial court dismissed the complaint on the ground that the remarks to the committee were absolutely privileged.

Reversing that decision, the appellate court said that the remarks enjoyed only a qualified privilege. The purpose of the Medical Studies Act was to improve the effectiveness of in-hospital peer group review by insuring that those providing information could speak freely. There was no purpose served by allowing one physician to defame another with impunity before a hospital executive committee.

The Act did not bar the physician's suit for defamation, the court concluded.—*Matview v. Johnson,* 388 N.E.2d 795 (Ill. App. Ct., March 7, 1979; rehearing denied, April 27, 1979)

Update on Professional Liability Planning by CSMS

ROBERT J. BRUNELL, M.A.

October 27, 1980. Responding to the "green light" given at the October 15 Council Meeting, the Committee on Professional Liability heard CSMS Consultant John Dorsett of American Health Systems, Inc., describe the detailed preparations necessary to ready alternatives to our present Professional Liability Program. CSMS Legal Counsel has already begun groundwork toward introducing legislation to charter a physician-owned "captive" insurance company in Connecticut. A second alternative will be to invite an existing out-of-state physician-owned company to operate a separately capitalized and separately rated program in our state. In connection with the first alternative, the Committee authorized a survey form to all present insured physicians to test the level of support for such a venture among the membership. Survey results should be available prior to the November 20 meeting of the CSMS House of Delegates.

Given sufficient enrollment, such "captive" mutuals can have a distinct pricing advantage by being able to discount future investment income on reserves off the premiums up front, and by eliminating certain expense factors of commercial companies. However, for the 1980-81 year, our own actuarial consultants tell us that this advantage would have been offset by the Aetna's having depressed rates below actual actuarial indications for Connecticut physicians, even with the 60% increase. Our consultants feel that the Aetna will be unable or unwilling to continue such concessions involving substantial paper losses beyond another year or so, and thus the Society should have an alternative ready for implementation on short notice, in order to responsibly protect the professional interests of our members, and to provide credible competition in the Connecticut market.

October 29, 1980. Representatives from CSMS Council, the Professional Liability Committee, and Staff met with Aetna representatives to continue to negotiate improvements in the present CSMS Professional Liability Program. This followed earlier separate meetings with the State Insurance Commissioner Joseph Mike. Aetna's initial offer included an improved investment income program which would return one half the money market rate (presently in the 12%-range) on invested reserves, compounded quarterly at the full rate. Presently our program has a $10 million underwriting deficit to work off before such income can be returned as dividends; the Aetna has offered to forgive this deficit entirely, and start the new investment income and excess premium return program fresh as of October 1, 1980. Finally, with a proviso that any rate increases during that time will be less than 35%; if not, then CSMS would be free to implement any alternative insurance source it has developed at any time, and without cancellation penalties. Following lengthy discussion, CSMS agreed to consider further data to be supplied by the Aetna, and to prepare a counterproposal for a future meeting. Now under preparation, this may include a proposal for discounting premium, and for retrospective risk-sharing.

ROBERT J. BRUNELL, M.A., CSMS Director of Scientific Affairs, staffs the Society's Committee on Professional Liability.

Searching the Literature and Computerized Services in Medicine

Guides and Methods for the Clinician

WILLIAM K. BEATTY, M.S.

Searching the literature does not have to be a time-consuming and frustrating chore. This paper describes fundamental methods, basic printed guides, and computerized services and tells how to obtain current information on computerized programs and their costs. These guides and services will lead the searcher to journal articles, books, papers delivered at meetings, audiovisual material, and other types of medical literature. They will also help to overcome the language barrier. The searcher for current literature will learn about, among others, the *Index Medicus* and the *Abridged Index Medicus*, MEDLARS and MEDLINE, *Current Contents, Science Citation Index*, and *Excerpta Medica*. The searcher for older material will learn about the "Index-Catalogue," "Garrison-Morton," *Familiar Medical Quotations*, and other helpful guides. Effective and efficient searching of the literature, whether by hand or machine, obtains two valuable commodities for the searcher: information and time.

Methods and guides for searching the literature of interest to the clinician have improved since 1973.[1] Some new services have started, and some old ones have expanded their coverage and added new elements. If you acquaint yourself with the basic printed guides, computerized services, and searching procedures you will find that you have acquired two valuable commodities: information and time.

Current Literature

The medical literature, especially the journals, has grown vigorously since the first journals—as we know them today—began publication in France and England 300 years ago. The National Library of Medicine (NLM) has reported[2] that 19,000 biomedical serials were appearing throughout the world in 1972.

The searcher for information in this vast outpouring of medical literature needs all available assistance. If you are planning a trip the first thing you need is a road map. If you are planning to search the literature you will need a similar guide. The basic road map for a search of the medical literature through the services of the National Library of Medicine is a publication called *Medical Subject Headings* (widely known as *MeSH*) which appears each year as Part 2 of the January issue of *Index Medicus; MeSH* will serve you efficiently as a road map for subject headings. It will tell you if the highway you plan to take is open or, if not, what alternative routes you can travel. It will give you useful route numbers, and it will even tell you what the inhabitants now call that little widening in the road that everyone used to refer to as Four Corners.

As one of the products of the NLM's Medical Literature Analysis and Retrieval System (MEDLARS) *MeSH* contains two major lists. The first alphabetizes all the subject headings and cross references the indexers use in putting together each issue of *Index Medicus*. You should take to this alphabetical list the most specific term you can apply to your topic. For example, you may be interested in cardiac arrhythmias and, more specifically, in the Wolff-Parkinson-White syndrome. Looking at the appropriate place in the alphabetical list (Figure 1) you will find this term given in large capital letters. Your *MeSH* road map has

WISSLER'S SYNDROME
C5.550.114.843.823 C5.799.825.823
C17.257.823 C20.543.928
65
X SUBSEPSIS ALLERGICA
X SUBSEPSIS HYPERERGICA
X WISSLER-FANCONI SYNDROME
WIT AND HUMOR
K1.517.946
X HUMOR
WITHDRAWAL SYMPTOMS see DRUG WITHDRAWAL SYMPTOMS
WITTENBORN SCALES see under PSYCHIATRIC STATUS RATING SCALES
WOLFF-PARKINSON-WHITE SYNDROME
C14.280.67.558.865

Figure 1

Section from Alphabetical List of *Medical Subject Headings (MeSH)* showing valid subject heading, Wolff-Parkinson-White Syndrome, and its code number for the Tree Structures. (From *Medical Subject Headings* 1979, p. 401.)

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told you that this road is open, that the indexers use this heading.

Two recent changes in the MEDLARS program are also apparent in Figure 1. The "65" under Wissler's Syndrome tells you that this heading has been used in *Index Medicus* since 1965 and, therefore, that the searcher for information on this subject may safely use this heading back through the 1965 *Cumulated Index Medicus.* At that point you would look in the New Terms list to find the proper heading (Rheumatism) for 1964. The cross reference just above Wolff-Parkinson-White Syndrome, "Wittenborn Scales see under Psychiatric Status Rating," conveys two items of information. It tells you that you will probably find the subject heading Psychiatric Status Rating in *Index Medicus.* However, because of recent changes in producing *MeSH* you should look up Psychiatric Status Rating in the Alphabetical List to make sure that it is a used heading and not another cross reference. The second item of information is that, although you will not find the heading, Wittenborn Scales, in *Index Medicus,* you will be able to search this term in the program "MEDLARS on-line" (MEDLINE), the computerized searching program.

The next searcher might be investigating blood groups, more specifically the Kidd Blood-Group System. The alphabetical list has this term also, but it is in small capital letters. The *MeSH* road map has informed this searcher that the planned road is not passable and that he must seek an alternate route. As a useful map should it gives this alternate route and tells the searcher that he should go under the broader term, "Blood Groups."

A third searcher may be seeking information on bacterial endocarditis. When he turns to the B part of the *MeSH* alphabetical list he does not find "bacterial endocarditis." However, a little readjusting of terms will suggest as an alternate heading, "Endocarditis, bacterial," and this turns out to be the key.

A search starts off, therefore, when you first ascertain the most specific term for your subject and then match it to the alphabetical list in *MeSH.* If you find a subject heading matching yours, you are well on the way. If you find a cross reference, look at the referred-to heading to make sure that it is a valid one. If you find nothing you then have three choices: inverting your term; taking the term up to the next more general level; or, finally, seeking help from the reference librarian in your local medical library.

One further step in *MeSH* may be helpful before you move on to the *Index Medicus* itself. To return to the Wolff-Parkinson-White Syndrome, you will see (Figure 1) a code number, C14.280.67.558.865, that will take you to the second of the two major lists in *MeSH.* This, the Tree Structures, shows the relations among all the terms used in a broad area. For example, Category C14 is entitled "Diseases—Cardiovascular." By scanning the three pages under C14 you will see all the subject headings the indexers have used in this area, and you may find one or more (that you had not thought of before) that will be helpful additions in your present search. The asterisks (Figure 2) after the terms "Asystole," "Sinoatrial Block," and "Carcinoid Heart Disease" indicate that these headings can not be searched in *Index Medicus* but can be searched in MEDLINE.

CARDIOVASCULAR DISEASES	C14
HEART DISEASES	C14.280
ARRHYTHMIA	C14.280.67
ARRHYTHMIA, SINUS	C14.280.67.93
ASYSTOLE •	C14.280.67.146
AURICULAR FIBRILLATION	C14.280.67.198
AURICULAR FLUTTER	C14.280.67.248
BRADYCARDIA	C14.280.67.319
EXTRASYSTOLE	C14.280.67.470
HEART BLOCK	C14.280.67.558
ADAMS-STOKES SYNDROME	C14.280.67.558.137
BUNDLE-BRANCH BLOCK	C14.280.67.558.323
SINOATRIAL BLOCK•	C14.280.67.558.750
WOLFF-PARKINSON-WHITE SYNDROME	C14.280.67.588.865
TACHYCARDIA	C14.280.67.845
TACHYCARDIA, PAROXYSMAL	C14.280.67.845.695
VENTRICULAR FIBRILLATION	C14.280.67.932
CARCINOID HEART DISEASE•	C14.280.129
	C4.557.112

Figure 2
Section from Tree Structures of *Medical Subject Headings (MeSH)* showing how the subject heading, Wolff-Parkinson-White Syndrome, fits into the listing for Cardiovascular Diseases. (From *Medical Subject Headings,* 1979, p. 504.)

Medical terminology is continually changing by addition, division, and subtraction. Just as the old familiar Four Corners may have become Jones City since you last drove through it, the subject term you have used successfully in the past may have been changed to match more closely current information and hypotheses. For example, if you had in the past searched through the list under "Amino Acids" while seeking references on "Amino Acids, Branched-Chain," you will now find your more specific interest matched by the indexer's new term. Two lists near the beginning of each annual *MeSH* enable you to move back and forth between the new and old terms that have recently been changed. At third list, designed for the prospective searcher, shows him which heading to change to if his earlier term is no longer being used.

Index Medicus

Armed with the right subject headings from your *MeSH* road map you can now go efficiently to the current issue of the *Index Medicus.* Subject searches are generally best made in reverse chronologic order enabling you to find the current material first. If you are lucky you will find a good recent review that may save you considerable time and effort.

The *Index Medicus* has two major sections and several smaller but also valuable parts. The Subject section lists references under general headings and more specific subheadings. By carefully using these subheadings you will be able to save much effort. The second major section, Author, lists authors and the personal subjects of biographic articles and obituaries.

The valuable small parts at the front include subject and author indexes to reviews; each reference gives the number of citations listed by the review's author as well as full bibliographic information for the review. The front matter of each issue also contains lists of the regional medical libraries, foreign MEDLARS/MEDLINE centers, and some recent literature searches made at NLM. This latter list can be specially useful if a search has recently been made in one of your areas of interest. All you have to do then is write to the address given, ask for a copy of the list by number, and it will be sent to you free.

Your reverse-chronologic search of *Index Medicus* will eventually bring you back through the January issue of the current year. The next step is to the bound *Cumulated Index Medicus.* Each annual set (the one for 1977 contains 14 volumes or "books") combines the information from the previous 12 monthly issues so that each subject heading or author entry will list a complete index-year of references in that one place. In addition to the saving of time brought about by this cumulation, you will benefit from an examination of the arrangements within *Index Medicus* that will now become evident with 12 times the amount of material available.

Under each subject heading you will find general articles listed first, for example, "Lipodystrophy, Intestinal" (Figure 3). More specialized articles are often listed under subheadings, for example, "Complications." The articles in English are given first and are listed alphabetically by the title of the journal. An article on "Lipodystrophy, Intestinal—Complications" in *Annals of Neurology* will appear ahead of a similar paper in *Medicine (Baltimore).* Articles in non-English languages follow those in English and have their references contained within square brackets. These references are listed alphabetically by language: an article in French precedes one in German on the same subject. Within each language group the references are again alphabetized by title of the journal. Knowing these arrangements can save you much time, effort, and frustration if you want to limit your search to specific journals that are immediately accessible to you or to those languages you can read with productive, even if not graceful, results. If an article in a non-English language contains an English abstract or summary this fact is noted in the *Index Medicus* reference; this means that you might profit from an examination of that article even though you do not read the original language. If the English version of the article's title was translated by the author this is also noted in the citation.

LIPODYSTROPHY, INTESTINAL

Whipple's disease. Leichtentritt KG. Am J Proctol 28(2): 59-62, Apr 77

COMPLICATIONS

Whipple's disease with predominantly neuroophthalmic manifestations. Finelli PF, et al. Ann Neurol 1(3):247-52, Mar 77

Neurologic disease in patients with treated Whipple's disease. Knox DL, et al. Medicine (Baltimore) 55(6):467-76, Nov 76

[Sarcoidosis and Whipple's disease. Association? Relation?] Pequignot H, et al. Ann Med Interne (Paris) 127(11): 797-806, Nov 76 (Eng. Abstr.) (Fre)

[Joint manifestations of Whipple's disease] d'Eshougues JR, et al. Rev Rhum Mal Osteoartic 43(10):565-73, Oct 76 (Eng. Abstr.) (Fre)

[Persistent diarrhea in rheumatic disease] Rosch W, et al. Fortschr Med 94(17):1004-11, 10 Jun 76 (Eng. Abstr.) (Ger)

[Neurological manifestations of Whipple's disease] Feurle GE, et al. Schweiz Med Wochenschr 106(47):1642-6, 20 Nov 76 (Eng. Abstr.) (Ger)

Figure 3
Section from Subject Index of *Cumulated Index Medicus* showing heading "Lipodystrophy, Intestinal," and subheading, "Complications." (From *Cumulated Index Medicus.* 1977;18(11):8799.)

The first book of each year's set of the *Cumulated Index Medicus* includes some valuable information. The 12 monthly sections of *Bibliography of Medical Reviews* are cumulated in the first or second book. The *MeSH* for that year is included. The 2600 journals indexed in *Index Medicus* are listed by abbreviation and full title. The list by abbreviation is helpful if you are trying to expand a confusing reference; the list by full title gives you access to the proper abbreviations to use for the references you will be citing in your own paper. A separately issued publication, *List of Journals Indexed in Index Medicus,* also lists these journals by subject and country of publication.

In addition to the journals, the *Index Medicus* has for several years indexed a few multiauthored monographs (most of which are proceedings of meetings). These are listed in the front of each issue and cumulated set. The citations for these are listed under the various headings and subheadings as though they were in journals whose titles begin with the letter I, because each monographic title is preceded by the word "In."

Abridged Index Medicus

If you want to obtain information from only those journals that are in English and are available in most areas—if not in most libraries—you should use the *Abridged Index Medicus,* which covers about 120 journals (primarily clinical) from the United States, Canada, England, and several other countries. This helpful monthly index also has an annual cumulation.

Medlars

The National Library of Medicine has pioneered in computerized control of the medical literature. Modern machine methods were first applied to the production of the *Index Medicus* in the mid 1960s. Production with the aid of computers led to the capability of searching the literature with computers. The original MEDLARS program has gone through several changes, and the current system is accessible through terminals in more than 600 institutions. Call your local or regional medical library to find out if such a terminal is available and to what data bases your terminal provides access. You will be able to search these data either directly or with the aid of a member of your library staff who has been trained by the NLM. Charges for searches vary in different institutions.

The major advantages or disadvantages of a computerized search in relation to the manual search vary from topic to topic. The advantages generally include access to more recent materials; use of more subject headings; availability of age, sex, geographic, and other subheadings that are not in the printed index; and increased speed, especially for topics that combine subject headings in such a way that the manual search could not easily provide, or even permit, the same combination.

Before you can have a computerized search run through the NLM programs you will have to engage in some planning with the operator of the terminal. The two of you will work out the appropriate subject headings (just as you did with *MeSH* for your manual search) and the pertinent combinations of these terms by using "and," "or," and "not," the vital three little words of contemporary information processing.

Many data bases are accessible through the NLM (Table 1). These include MEDLINE (a computerized approach to some of the journals in *Index Medicus*), TOXLINE (makes available references to human and animal toxicity studies and related material), CANCERLIT (and several other disease-oriented data bases), and MEDLEARN (a computer-assisted instruction program that demonstrates how to use MEDLINE).

Computerized programs are valuable for making you quickly aware of the contents of the relatively current medical literature, but there are also nonmachine techniques and printed guides you can use to keep yourself up to date.

After completing a search, look over your references and note the journals that provide most of them. You have thus identified several journals that regularly publish articles of interest to you. Next, go to the current-journal shelves of your local library and look through the issues of those journals that have been printed since the last issue of each journal appeared in the *Index Medicus.*

Current Contents

Current Contents, one of several valuable publications from the Institute for Scientific Information, will also help you keep current. This weekly journal, which appears in seven editions (including *Life Sciences, Clinical Practice,* and *Social & Behavioral Sciences*), reproduces the tables of contents of hundreds of journals. Each issue has a subject index and an author index, which not only refers you to an article by that author but also gives the author's address so you can immediately request a reprint. Each issue now contains a list of the journals covered by that edition, an important element if you want to be sure you are covering specific journals. By skimming over the tables of contents of the pertinent journals in one or two editions of *Current Contents* each week, you will be

Table 1

SOME OF THE SEARCHABLE DATA BASES AT THE NATIONAL LIBRARY OF MEDICINE*

Data Base†	*Total Records*	*Dates Covered*
	no.	
1. AVLINE‡	6908	Through 1979
2. BACK66	501 802	Jan 66-Dec 68
3. BACK69	668 258	Jan 69-Dec 71
4. BACK72	669 109	Jan 72-Dec 74
5. BACK75§	642 954	Jan 75-Dec 76
6. BIOETHICS‡	7129	Jan 73-Dec 78
7. CANCERLIT‡	159 167	Jan 63-Mar 79
8. CANCERPROJ‡	21 646	1976-1978
9. CATLINE‡	185 070	1965-1979
10. CHEMLINE	362 537	—
11. CLINPROT‡	1168	—
12. EPILEPSY‡	24 177	1945 present
13. HEALTH‡	109 460	Jan 75-Apr 79
14. HISTLINE‡	34 728	—
15. MEDLINE	451 834	Jan 77-Apr 79
16. RTECS‡	33 929	1978
17. SDILINE	20 018	Apr 79
18. SERLINE‡	31 832	1979
19. TOXLINE‡	548 725	—
CBAC	294 554	1974-1979
TOXBIB	113 173	1974-Mar 79
IPA	31 631	1974-Oct/Nov 78
HEEP	69 281	1974-Mar 79
PESTAB	15 571	1974-Mar 79
EMIC	22 792	1960-1978
ETIC	11 600	1960-July 78
20. TOXBACK‡	379 299	—
CBAC	167 668	1965-1973
TOXBIB	127 104	1968-1973
IPA	19 188	1970-1973
HEEP	24 680	1971-1973
HAPAB	12 816	1966-1973
HAYES	10 043	1940-1966
TMIC	4552	1971-1975
TERA	13 248	1960-1974

*Adapted from *NLM Technical Bulletin,* March 1979, p. 2. Numbers 2 through 5 are earlier files of MEDLINE material. No. 17 consists of the current citations that have not yet been printed in *Index Medicus.* No. 9 contains cataloguing information for books recently catalogued and some location information for libraries other than NLM. No. 18 is roughly the serials equivalent of No. 9. No. 10 is an on-line chemical dictionary. No. 11 is part of the cancer data base. No. 13 is basically the data base for the *Hospital Literature Index.* No. 14 is for the history of medicine. No. 16 is the Registry of Toxic Effects of Chemical Substances. Nos. 19 and 20 are collections of data bases dealing with toxic effects.

†CBAC = Chemical-Biological Activities, IPA = International Pharmaceutical Abstracts, HEEP = Abstracts on Health Effects of Environmental Pollutants, PESTAB = Pesticides Abstracts, EMIC = Environmental Mutagen Information Center File, ETIC = Teratology Information Center File, HAPAB = Health Aspects of Pesticides Abstracts, HAYES = Bibliographic collection on pesticides formed by W.J. Hayes, Jr., TMIC = Toxic Materials Information Center File, TERA = Teratology File.

‡Files available only through National Library of Medicine (NLM).

§Citations with publication year of 1976 or earlier but entry date of 1977 or 1978 also included. The BACK files are available only by off-line search through NLM and State University of New York (SUNY). TOXBACK is available only by off-line search through NLM.

able to keep an eye on what many journals are printing. The Institute for Scientific Information offers a variety of manual and computerized services that might also be helpful to you. Their address is given, along with those of other services, in Table 2.

Table 2

COMPUTERIZED SERVICES FOR LITERATURE SEARCH

BioSciences Information Service, 2100 Arch Street, Philadelphia, PA 19103 (215-568-4016)

BIOSIS will perform individually-designed searches of their files back through 1959. An estimate of the cost will be made after the requester has filled out and sent in the appropriate form. The printout can include citations or abstracts. Current Awareness searches on one of 28 topics can be done on the current file once a month (Standard Profiles—at $60 per year per topic) or three times a month (Current Literature Alerting Search Service—at $210 per year per topic, renewal rate, $150).

Chemical Abstracts Service, P.O. Box 3012, Columbus, OH 43210 (614-421-6940)

CAS does not perform searches directly. Write or call them for a list of the organizations that have been licensed to use their computer-readable files.

Excerpta Medica, 3131 Princeton Pike, Lawrenceville, NJ 08648 (609-896-9450)

The Excerpta Medica data base (EMBASE) is available on-line through the Lockheed DIALOG system which is accessible with any standard terminal. Searches on this data base, which runs from April, 1975, through the present, can produce citations or abstracts at a basic rate of $55 per connect hour.

Institute for Scientific Information, 3501 Market Street, Philadelphia, PA 19104 (215-386-0100)

The Search Service performs retrospective searches of its data bases at a basic fee of $75 a search. The Automatic Subject Citation Alert (ASCA) current awareness service provides weekly reports at a typical annual fee of $170 (depending on the profile for the individualized search). Trial programs for new ASCA subscribers are available at $39 for 13 weeks. SCISEARCH, which covers the data from several years of the *Science Citation Index* and *Current Contents,* is available online through the Lockheed DIALOG system.

Psychological Abstracts Information Service, American Psychological Association, 1200 Seventeenth Street, N.W., Washington, DC 20036 (202-833-7600)

The data base includes material published in *Psychological Abstracts* from 1967 through the present. Retrospective searches will produce lists of citations. The charge for a typical search ranges from $40 to $60. The requester will be notified if the cost will exceed $100.

Smithsonian Science Information Exchange, Inc., Room 300, 1730 M Street, N.W., Washington, DC 20036 (202-381-4211)

SSIE will search its active file for Notices of Research Projects on specific subjects at a basic rate of $50 a search. The Exchange also performs Selective Dissemination of Information searches either monthly or quarterly for $180 a year. Historical searches cover the five years prior to the active file at a per item charge. The SSIE data base is also available on-line to users who have access to a computer terminal.

Toxicology Information Response Center, Information Center Complex, Post Office Box X, Oak Ridge, TN 37830 (615-576-1743)

TIRC performs retrospective searches on a wide variety of data bases. Continuing searches for current material can be arranged on a fee-for-service charge. The basic rate is $30 per hour for domestic requests.

Meetings

Many papers are first given at meetings, and frequently these do not appear in a proceedings volume or in the regular journal literature for months or even years. Nevertheless, you can often locate references and information concerning these papers by consulting guides to meetings such as *InterDok (Directory of Published Proceedings)* and the Institute for Scientific Information's new *Index to Scientific & Technical Proceedings.* Another guide for meetings, *Conference Papers Index,* published monthly with detailed quarterly indexes, carries you one step farther by indexing many papers from the final programs of meetings or from volumes of abstracts issued before the meetings are held.

Many other useful indexes exist, and a consultation with your local medical reference librarian will probably result in the suggestion of some additional pertinent items. These may range from the American Medical Association's *Medical and Socioeconomic Research Sources* to annual listings of research projects and investigators such as the *General Embryological Information Service.* Your librarian may decide that a computerized service is the most suitable for your needs; an example is the Smithsonian Institution's Science Information Exchange, which contains information about researchers and their work in the medical and biological sciences (*see* Table 2).

Excerpta Medica

Abstracting journals give more information than indexing journals, although they generally pay for this increased material by needing a longer time for the editorial and printing facets of publication. A good abstracting journal will offer you three basic approaches to the literature. You can use it for keeping up, searching, and for overcoming the barriers of language.

Excerpta Medica is divided into 42 subject sections (Table 3), each of which appears 10 to 12 times a year. There is a section for each basic and clinical science, and other sections deal with specific diseases, a group of diseases, or with general areas. For example, if you want to keep up with much of the important work on supraventricular and nodal arrhythmia being reported in medical journals throughout the world, select the appropriate subject section, *Cardiovascular Diseases and Cardiovascular System,* and examine the table of contents on the inside of the front cover. You will find that the subheading "Supraventricular and Nodal Arrhythmia" has the code number 11.2 and that abstracts of articles on that subject appear on the pages listed next to that code number. This means that if you take a few minutes to look at each issue of that subject section as it appears, and read the abstracts in Part 11.2, you will find pertinent material selected from thousands of journals.

You can search individual issues of *Excerpta Medica* or the annual bound volumes by using the subject

Table 3

SUBJECT SECTIONS IN *EXCERPTA MEDICA*[*]

Anatomy, Anthropology, Embryology, and Histology
Anesthesiology
Arthritis and Rheumatism
Biophysics, Bio-Engineering, and Medical Instrumentation
Cancer
Cardiovascular Diseases and Cardiovascular Surgery
Chest Diseases, Thoracic Surgery, and Tuberculosis
Clinical Biochemistry
Dermatology and Venereology
Developmental Biology and Teratology
Drug Dependence
Endocrinology
Environmental Health and Pollution Control
Epilepsy
Forensic Science
Gastroenterology
General Pathology and Pathological Anatomy
Gerontology and Geriatrics
Health Economics and Hospital Management
Hematology
Human Genetics
Immunology, Serology, and Transplantation
Internal Medicine
Microbiology: Bacteriology, Mycology, and Parasitology
Neurology and Neurosurgery
Nuclear Medicine
Obstetrics and Gynecology
Occupational Health and Industrial Medicine
Ophthalmology
Orthopedic Surgery
Oto-, Rhino-, Laryngology
Pediatrics and Pediatric Surgery
Pharmacology and Toxicology
Physiology
Plastic Surgery
Psychiatry
Public Health, Social Medicine, and Hygiene
Radiology
Rehabilitation and Physical Medicine
Surgery
Urology and Nephrology
Virology

[*] *See* text for discussion.

and author indexes in each. The language problem becomes less of a hurdle, because all of the abstracts are in English even though many of the original articles are in non-English languages.

The Excerpta Medica Company also has a broad computerized program that can be used in several ways. Write to them at the address listed in Table 2 for additional information and charges.

Abstracting and Indexing Services

Medicine is no longer the neatly circumscribed field it was when a Benjamin Rush or a Daniel Drake was a medical student or an apprentice taking care of his master's office and horses and preparing some of the medicines. The current searcher for medical information must be acquainted with such printed publications as *Chemical Abstracts, Biological Abstracts, BioResearch Index,* and *Psychological Abstracts* and their manifold computerized services.

Chemical Abstracts includes a vast amount of material, a portion of which is related to clinical medicine. It began publication in 1907 and now appears weekly with two alternating issues. The first deals with biochemistry and organic chemistry, whereas the second covers macromolecular and applied chemistry, chemical engineering, and physical and analytical chemistry. *Chemical Abstracts* covers thousands of journals and many books, reports, and patents. It will substantially increase your coverage of the medical and related literature. Each issue has Keyword, Numerical Patent, and Author Indexes and a Patent Concordance that relates new patents to those already abstracted. A series of cumulated indexes saves the searcher great amounts of time. The first five cover 10 years each and the next four (beginning with the sixth, 1957-1961) cover 5 years each.

Biological Abstracts also covers material of clinical medical interest. It includes thousands of journals, book reviews, letters, and notes. Begun in 1926, *Biological Abstracts* is now produced on a semimonthly basis. Each issue has Author and Subject Indexes; Biosystematic Index (by Phylum, Class, Order, and Family); Generic Index (by Genus and Species); and a Concept Index (for relating broad subject areas). Although *Biological Abstracts* has no cumulated indexes, each volume has its own indexes.

BioResearch Index, a complementary publication to *Biological Abstracts,* includes a substantial amount of material pertinent to clinical medicine. Now a monthly publication, *BioResearch Index* has appeared under this title since 1967. It covers many journals, annual reports, bibliographies, books and chapters, and several other types of publications. Each issue and volume have the same indexes as those found in *Biological Abstracts.*

Psychological Abstracts covers much material of clinical medical interest. Begun in 1927, it is now a monthly publication that includes many journals, technical reports, monographs, and other types of literature. It has two major cumulated indexes, each one having a series of supplements. The Author Index covers the *Psychological Index* (1894-1935) and *Psychological Abstracts* (1927-1958). There are supplements for 1959-1963, 1964-1968, 1969-1971, and 1972-1974. The Subject Index covers 1927-1960 with supplements for 1961-1965, 1966-1968, 1969-1971, and 1972-1974.

When you first examine any indexing or abstracting journal that is new to you, be sure to read introductions or prefaces carefully, examine the types of indexes these journals have (subject, author, biosystematic, and so forth), and look around the neighboring shelves for any cumulated indexes that conveniently combine 5, 10, or some other number of years of material.

Books and Audiovisuals

Books and audiovisual materials can also be useful. Two basic publications provide helpful information: the *National Library of Medicine Current Catalog* and Bowker's *Medical Books and Serials in Print.* The *Current Catalog,* issued quarterly with an annual cumulation, indexes recently published books by subject and author and until 1978 also included much helpful information on films, cassettes, and other audiovisual items. Beginning in 1978 a separate publication, *National Library of Medicine Audiovisuals Catalog,* has dealt solely with audiovisual materials.

The Bowker publication, an annual listing of books in English by subject, author, and title, increased its coverage of the medical literature in 1978 by listing serials as well. This guide gives full bibliographic information and cost for books and serials, and for the latter sometimes gives circulation figures and the titles of indexing and abstracting journals covering that serial.

Older Literature

If you need to go back into the literature before 1960 (when the current series of the *Index Medicus* began), you will consult the *Current List of Medical Literature* (for 1952-1959), *Quarterly Cumulative Index Medicus* (1927-1956), *Quarterly Index to Current Medical Literature* (1916-1926), and the first three series of *Index Medicus* (1879-1899, 1903-1920, 1921-1927). You should also look at the 61-volume set entitled *Index-Catalogue of the Library of the Surgeon General's Office.* This Army publication came from the predecessor of the current National Library of Medicine. The "Index-Catalogue" in its five series provides the searcher with access by author and subject to books and by subject to journal articles for millions of pieces of the medical literature. This is a gold mine with which any serious searcher of the medical literature should become thoroughly familiar.

If you are interested in the historical development of a medical subject you will find valuable *A Medical Bibliography (Garrison and Morton)* edited by Leslie T. Morton; the third edition (1970) is available from J.B. Lippincott Company. This reference work lists chronologically under each subject the books and articles that are important in the growth of that subject. Many of the entries are annotated. "Garrison and Morton" is the volume for a searcher who wants to know the important persons in a field, in what publications major events are reported, and how to locate these vital contributions bibliographically.

Perhaps you have a partially remembered quotation in mind or want to find a quotation that will sum up or underline your point or thesis. In these frustrating cases you should consult *Familiar Medical Quotations,* edited by Maurice B. Strauss and published by Little, Brown and Company in 1968. For example, if you want to identify and quote correctly

> Attempt the end, and never stand to doubt;
> Nothing's so hard, but search will find it out

you will find in *Familiar Medical Quotations*[3] that Robert Herrick, the seventeenth-century English poet, wrote this two-line poem which is in his collection, *Hesperides.*

Science Citation Index

Throughout this paper we have been either searching back into the older literature or attempting to keep up with the current literature. A major publication, *Science Citation Index,* produced by the Institute for Scientific Information, offers you the opportunity of seeing how ideas, methods, and hypotheses have fared after they have been described in the literature. The *Science Citation Index,* which began in 1961, shows who is citing whom (Figure 4). It lists by author all the references cited in some 3300 journals and more than 1000 new books annually; there is a separate subject index. This means, for example, that if you have found a particular article of help in your work, all you have to do to see how later authors haved added to the material in that article, modified it, or even contradicted it, is to look up the author's name in the current quarterly or annual issue of *Science Citation Index* and examine the listed articles that have recently cited the original article of interest to you. Two 5-year cumulations, 1965-1969 and 1970-1974, will help you save time. The *Science Citation Index* opens many useful paths for investigating the literature.

BARACH AL				
21 ARCH INTERNAL MED 28 421				
AUERBACH D	CHEST	74	39	78
38 ANNALS INTERNAL MED 12 454				
AUERBACH D	CHEST	74	39	78
SPRIGGS EA	BR J DIS CH R	72	165	78
38 ANNALS INTERNAL MED 12 754				
BREDENBE CE	ANN THORAC	26	62	78
RICHARDS CP	PEDIAT RES	12	771	78
SEWELL RW	ANN THORAC	26	126	78
STAUB NC	CIRCUL RES R	43	143	78
41 AM J MEDICAL SCI 202 336				
ORREGO H	LAB INV	38	633	78
66 ANN ALLERGY 24 51				
BRADLEY BL	AM R RESP D	118	239	78
66 CONTROVERSY INTERNAL 421				
NEWTON DAG	LANCET	2	228	78
68 ANN ALLERGY 26 10				
DERENNE JP	AM R RESP D R	118	119	78

Figure 4

Section from Citation Index of *Science Citation Index* showing references to seven papers by A.L. Barach. The second and third entries under Dr. Barach's name indicate that he published two papers in *Annals of Internal Medicine* in 1938 and that these two papers were cited a total of six times during the third quarter of 1978 in journals covered by *Science Citation Index.* The third entry indicates the citations for the paper by Dr. Barach published in *Annals of Internal Medicine,* volume 12, beginning page 754: "Positive Pressure Respiration and Its Application to the Treatment of Acute Pulmonary Edema." This paper was cited by C.E. Bredenberg, C.P. Richards, R.W. Sewell, and N.C. Staub in 1978 in four papers in three different journals. (From *Science Citation Index,* Citation Index, A-KOZL, July/Sept 1978, col. 33376).

In 1969 the Institute started the *Social Sciences Citation Index* (5-year cumulations for 1966-1970 and 1971-1975) and in 1977 the *Arts & Humanities Citation Index.* One or both of these may also be helpful to you.

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3. Strauss MB, ed. *Familiar Medical Quotations.* Boston: Little, Brown and Company; 1968:498a

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Month in Washington

In the Congress' mad rush to recess and get out on the hustings it has paid little attention to specific health related legislation. The budget reconciliation process has imposed added strain to a system now groaning under the weight of trying to do too much in too little time. As a result many measures of importance to medicine may die on the vine.

****

In the face of opposition from many in the medical research community, the House has easily approved historic legislation greatly extending Congress' control over the federal medical research effort at the National Institutes of Health (NIH).

The National Cancer and Heart and Lung Institutes, formed during the past decade, are subject to the Congressional authorization procedure, but the rest of NIH has remained unencumbered. As a result, the health subcommittees of the Senate Human Resources Committee and of the House Commerce Committee have not been able to exert the type of oversight and control of NIH activities that are enjoyed by most non-appropriations committees.

Many researchers have feared that authorization authority could lead to more political dabbling in NIH activities and possible restrictions on funding.

In an effort to meet these objections, the House bill allows authorizations to be provided for an additional year automatically if program extensions unavoidably are delayed; and sets up an overall authorization of $100 million to assure that unexpected breakthroughs in research would not be impeded by limits in authorization levels.

Although the appropriations committees have great leeway in voting funds, they are limited by law from exceeding authorization levels established by the other commitees in Congress.

The issues raised by the legislation were serious enough for opposition to be registered by four former assistant HEW Secretaries for Health, four previous directors of NIH, the American Association of Medical Colleges and the Association of Professors of Medicine, among others.

However, supporters of the bill, led by Commerce Subcommittee chairman Rep. Henry Waxman (D-Calif.) and ranking GOP member Tim Lee Carter, M.D. (R-Ky.), noted that the Surgeon General and current Assistant Secretary for Health, Julius Richmond, M.D., and Donald Frederickson, M.D., director of the NIH, have indicated their backing of the measure.

But Capitol Hill observers believe there is little chance differences between the Senate and House version of the bill can be ironed out in the rush to recess. Nonetheless, sponsors of the controversial legislation promise they will be back with the same proposal in the next Congress.

****

The government has opened a pilot program of requiring drug manufacturers to provide patient package inserts for 10 drugs or classes of drugs. The purpose is to determine whether such inserts are a good way of informing the public and whether more drugs should be covered.

Pharmacists will provide the leaflets when a prescription is filled initially.

The drugs involved are ampicillins, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, thiazides, phenytoin, propoxyphene, and warfarin.

The three-year program will cost an estimated $21 million a year which will be borne by the manufacturers. Each pamphlet will cost about 18 cents, a cost that will be reflected in the cost of the drug. The Pharmaceutical Manufacturers Association said the federal action is "an important first step" toward the objective of getting meaningful information to the consumer.

The "inserts" will describe what the drug is for, what side effects may occur and how to take the drug properly to get the most benefit. The leaflets—scheduled to be available in pharmacies by mid-1981—will also be available to hospitals and nursing homes.

The drugs chosen for the pilot program include some of the most frequently prescribed, including the benzodiazepine category of tranquilizers which numbers librium and valium among the familiar name brands. About 16 percent of all new prescriptions would be affected.

Health and Human Services Secretary Pat Harris told a Washington, D.C. news conference that many of the six million cases of adverse drug reaction could be prevented or minimized by giving patients more information about their prescription drugs.

During the evaluation period, the FDA will permit the testing of alternative methods such as having drug information available in a book at the pharmacy.

Prepared by the Washington, D.C.
Office of the American Medical Association

Under the benzodiazepines, the guideline insert includes both a statement that special precautions apply to the use of the drug in elderly patients and a statement about the risk of the patient developing a dependence on the drug. These drugs should not be used to treat anxiety or tension due to the stress of everyday life, the leaflet says. It cautions against using alcohol while taking the drugs.

Warning on dependence and use with alcohol and other drugs are also featured in the propoxyphene insert. Advice is given in case of an overdose.

Caution against exposure to sunlight is given for methoxsalen.

Patients taking phenytoin are urged to watch out for signs of toxicity. A similar warning of toxicity is included for digoxin.

Clifibrate may increase the risk of having gallbladder trouble or getting tumors, according to the leaflet. Regular blood tests are urged.

Warfarin can dangerously interact with other drugs, even aspirin, patients are notified. Physicians should be told of unusual bruising or bleeding.

In a rule published in the Federal Register September 12, FDA set forth the new requirements and published draft guidelines for the ten patient package inserts.

****

The American Medical Association has told Congress the National Health Service Corps (NHSC) program should not become the primary means of financing medical education through federal scholarships. At the same time, the AMA supported the goals of the program in providing medical personnel to "truly underserved" areas.

Joseph Boyle, M.D., Vice Chairman of the AMA Board of Trustees, told the Senate Labor Subcommittee on Health that the AMA sees problems with the Corps in the designation of shortage areas and in the placement of corps personnel. "A significant step to alleviate these problems would be to allow input in the placement of corps personnel from local medical societies," Dr. Boyle said.

Such input could also have the advantage of increased cooperation between practitioners and work to increase the retention rate of corps personnel in the communities where they are placed."

Dr. Boyle said that as more studies are completed it will be easier to plot the future of the corps. Until such studies are completed, there should be no increase in the number of NHSC scholarships, he added.

"For the corps to be most effective, it must work as an adjunct to the physician in private practice," said Dr. Boyle, "only through the proper allocation of corps personnel will health manpower shortage areas be eliminated."

****

The Senate has passed and sent to an uncertain fate the health education assistance bill which discontinues the present capitation aid program for medical schools.

The bill, which had been dangling for months, was approved with only brief comment and by voice vote.

The House-passed medical education bill is substantially different, proposing a three-year phase-down of capitation aid, among other provisions.

The Senate measure proposes a new national priority incentive grant program starting in fiscal 1982 under which schools which undertake certain projects—such as conducting a certain percentage of clinical education in shortage-areas—would receive grants amounting to $250 per student.

The shortage of time left before the election recess may cause the final congressional disposition of the bills to be put off until a lame duck session after the elections or the legislation may be shelved for this year with a continuing resolution to keep education funds flowing at their current level for another year. In this event, the new Congress would have to tackle the issue again next year.

****

The House has passed legislation protecting news media offices from arbitrary searches for evidence by federal officials. The measure also called for the Attorney General to draw up guidelines to prevent such search warrants where they would intrude on the confidential relationship between physician and patient and attorney and client.

The AMA had urged that the bill, similar to one approved by the Senate earlier, cover the medical profession as well as the news media in the mandated protection. However, the bill's backers decided to limit the protection to the first amendment—freedom of speech—area.

The Supreme Court in 1978 broadened the scope of search warrants against innocent third parties by imposing a standard of "reasonableness" in a decision that sparked a flood of protest from the news media. The case stemmed from a police search of the files of the Stanford U. newspaper.

The legislation essentially would overturn the decision as it applies to the press.

All of the witnesses at the hearings, including the press, urged that the protection be extended to all innocent third parties, but the Justice Department expressed reservations about such an extension beyond the news media.

The President's Page

For the third consecutive year polls show that the number one concern of American physicians is the rising cost of medical care. Concern about the increased cost of care is shared by everyone. Solutions are not easy and many proposals seem threatening to physicians. Some insight into what changes may be in store can be gained if we consider who *really* cares about the cost of medical care.

We, as physicians, are not threatened by any real financial loss as a result of rising costs. Our concern is for the welfare of our patients who find the costs of hospital and ancillary services increasingly burdensome. We are also concerned about our role in directing increasingly expensive care. These concerns, however, do not have the force of potential economic loss and physicians are not a potent factor in promoting changes.

The vast majority of patients having their expenses paid by third party payers are not really aware of the burdens of escalating costs. Prepaid medical insurance, unfortunately, like installment buying, removes the awareness of the true cost from the consumer. The consumer, then, has not as yet exerted much pressure for change.

At first glance the Blues, commercial insurance companies, and various prepaid plans would appear to be very much concerned since they pay the bills. However, the higher bills simply mean higher premiums which means more dollars handled by the carriers therefore more employees (more salaries!) and more business . . . and, for private companies, perhaps more profit. Unless changes threaten the third party payment system, the carriers have no strong motivation for bringing about reduction in costs.

It seems obvious, then, that neither the health industry, the insurance industry nor the consumer will be a major factor in promoting change, even though these are the agencies usually considered to be prime movers in health care planning. There are two directions from which we can expect real pressure. *Government* now pays 30% of all hospital bills and other medical costs. *Industry* pays the major portion of the balance.

We are all aware of the direction being pursued by the government to control costs. The unexpectedly high costs of Medicare and welfare are forcing legislative bodies to seek relief in every direction from increased regulations, cost control, rationing of care and other methods, none of which have yet proven satisfactory.

In a lecture at the National Leadership Conference of the AMA the president of the National Association of Manufacturers emphasized the immense cost of medical care to industry. Large industries spend, not just millions, but tens and even hundreds of millions of dollars annually for health care alone. Industry pays about 90% of employees medical care costs . . . over $1,000 per employee per year. This is a powerful reason to care about rising costs of health care. Whatever happens to change these costs, we can expect the National Association of Manufacturers and the National Chamber of Commerce to be equally or perhaps more concerned than government. It would be well for us to remember, in all our thoughts about the future of our health care delivery system, that these two agencies have the greatest concern with reducing costs.

Recent conversations with industry representatives indicate a great deal more interest and planning than most physicians realize. Consideration is being given to industry owned and operated health delivery systems, somewhat similar to HMO's, including major treatment centers and hospitals. The demonstrated reduction in hospitalization by HMO's is very attractive to industry. HMO's draw their membership from the healthiest age groups and therefore can outbid the Blues and most of the commercial plans which must cater to the population as a whole.

In order to plan for the future, physicians must recognize that the fringe benefit system with the employer picking up the cost of medical care has created a powerful new force which is working for changes in our health care delivery system. Failure to recognize the needs of industry could have serious consequences. The AMA is making some progress in joint study and planning with industry. Our state and county societies are lagging in this area.

W. Raymond James, M.D.
President

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Reflections from the Dean's Office

Lord Snow and Scientific Fraud

ROBERT U. MASSEY, M.D.

In his first novel, *The Search,* C.P. Snow gets to the heart of the ethical issues which face the scientific investigator. Although the story is set in the world of the twenties and early thirties, it is as true for today as it was then, and probably would have been true for Harvey 350 years ago, although a seventeenth century scientist might have told it differently.

Arthur Miles, the young physicist in the novel, has just discovered some data that will not fit:

> "I was wrong, irrevocably wrong. I should have to begin again.
>
> Then I began to think: If I had not taken this photograph, what would have happened? Very easily I might not have taken it. I should have been satisfied with my idea: everyone else would have been. The evidence is overwhelming, except for this. I should have pulled off a big thing. I should be made. Sooner or later, of course, someone would do this experiment, and I should be shown to be wrong; but it would be a long time ahead, and mine would have been an honourable sort of mistake." Later Miles reflects:
>
> "From that day I understood, as I never had before, the frauds that creep into science every now and then. Sometimes they must be quite unconscious: The not seeing of facts because they are inconvenient, the delusions of one's own senses."

Writing 25 years later in *The Two Cultures,* Snow says of scientists:

> "In the moral, they are by and large the soundest group of intellectuals we have; there is a moral component right in the grain of science itself—"

Do the conventions of science, truth telling and giving credit, inhering, as Snow believed, in the grain of science itself, run deep into the grain of the men and women who do science, shaping their characters and determining how the rest of their lives are lived? Or is it the other way around: are scientists simply those men and women who need to make painstaking observations and to tell the truth, who are driven by that moral imperative which is at the heart of science?

In *The Affair,* the eighth novel in the *Strangers and Brothers* series, written 26 years after *The Search* Snow tells a story of scientific fraud involving a faked photograph, a revered older scientist, recently dead, and an unappealing young investigator with an unpleasant wife and unpopular political convictions. Although Snow knows that moral, as well as legal, issues are at stake, he won't allow himself to moralize; he is telling a story, not doing a thesis on ethics. However, *The Affair* raises another issue: the responsibility of the institution, and the need to protect its good name and the honor of science. If fraud has been committed, discovered, and allowed to run no further, and the accused dismissed, is there any harm in covering up? What if there is new evidence that begins to suggest that the dismissal may have been wrongful? One Cambridge master thinks not:

> "And any unnecessary publicity about it, even now, is as near unforgivable as makes no matter. We've come out of it internally with no friction that I know of. And externally, better than any of us could have hoped. I do impress on you, this is a time to count our blessings and not disturb the situation."

Yet the situation was disturbed, of course; it had to be because, in the long run, in science truth counts for more, more even than in politics or the law, more even though philosophers find scientific truth hard to define. Governments may conceal facts as a matter of policy, invoking national security or the public interest; governments and industry have long-term objectives of power and profit that are different from those of science. More and more industry and government policy issues, however, involve science and technology, and then values may clash. Perhaps it will be the "moral component right in the grain of science itself" that will provide the saving grace for our technological culture.

Meanwhile, it might be better not to speak of research as a business or of science as a commodity to be marketed. Expressions like "the health care industry" imply an industrial model and the values that go with it. Like Lord Snow, we can avoid being self-righteous about that, simply observing that without its conventions of truth telling and giving credit, science will not work; government and the market place may conduct their affairs under dispensations.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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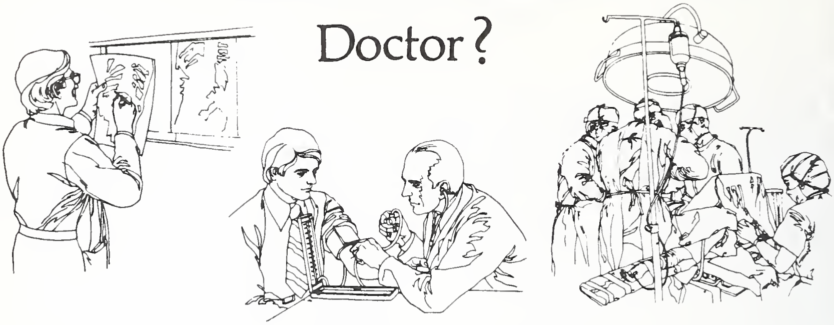

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EDITORIALS

The Renaissance of Nutrition

Good nutrition to some people means vague confidence that if you feel OK, the body's needs somehow are being met; don't worry about it. To others, concern about nutrition is a major component of a preoccupation with health. That preoccupation may be expressed in different ways. "I'm a health food freak" is not an uncommon one. Another way is expressed by those whose bottles of dietary supplements actually outnumber the essential nutrients: "I'm not taking any chances." These are the extremes; most Americans find themselves somewhere in the middle ground.

Is it any different with physicians? Probably not, but the physicians' attitudes should be shaped by knowledge of the science of nutrition, whereas public attitudes cannot necessarily be expected to reflect a foundation in science.

Physicians' attitudes about nutrition differ. An impressive number of clinical nutritionists and surgeons give nutrition a very high priority in their practice and their research interests. Other physicians seem to be unimpressed saying: "I've never seen an example of malnutrition in my practice." The former attitude expresses the renaissance that is occurring. Nutrition is awakening from a forty-year slumber that started when frank vitamin deficiencies finally were conquered. In the interim, metabolic pathways and cellular processes were being defined. We are now beginning to reap the benefits of that research, particularly in the management of critically ill patients. This is what the excitement in clinical nutrition is all about, i.e., management of the particular homeostasis characteristic of a disease process or severe trauma (burns, infection, major surgery).

Physicians dealing with the very ill patient are learning how to manage the departure from normal homeostasis and how to create a metabolic set that is most appropriate for the condition being treated. We are now approaching the most sophisticated period in the history of clinical nutrition. The ability to bypass the traumatized G1 tract, (with all of its barriers to nutrient absorption and digestive idiosyncrasies) has provided research opportunities for learning much more about the metabolic effects of nutrients. While relatively few physicians will ever have occasion to avail themselves of the procedures involved with parenteral alimentation, all will reap the benefits of the knowledge being gained by utility of the procedure.

Paralleling the developments in parenteral nutrition have been advances in the technology of tube feeding by way of gavage through nasopharangeal intubation or direct entry of the stomach or duodenum by cannula. Thus, we now have available the means to nourish patients no matter what the circumstances. Ruberg touches on these advances in his paper in this issue on p. 713.

The point being made is that while all physicians need not be experts in the newest nutritional techniques, they should be aware of what can now be accomplished with the patient who is difficult or impossible to feed by conventional means.

What about the attitude expressed earlier, "I've never seen an example of malnutrition in my practice"? How do we deal with that? The human is endowed with a biological latitude that equips him with the ability to withstand short-term deficits in nutrient and energy intake without obvious manifestations of ill health. Should stress be imposed, clinically observable signs of deficiency may surface. In case the stress is sufficient to require hospitalization, continued poor nutrient intake could place the patient in jeopardy. In other words, the malnutrition in hospitals cited by Ruberg, may, in many instances, have been developing prior to hospitalization. Delay in instituting appropriate therapy pushed the patient into clinically observable malnutrition. Subtle malnutrition is more often discernable by biochemical or immunologic tests than by visual observation. And thus the statement: "I've never seen a case of malnutrition," . . .

Strictly speaking, every physician treating an obese patient is dealing with malnutrition. The gross energy imbalance, quite apart from any concurrent nutrient deficits (or excesses), represents the most common form of malnutrition in the country. The usual obese subjects have probably tried most of the crash weight reduction diets and in the process have subjected themselves to more nutritional abuses. The uncontrolled mass experiments with grossly imbalanced diets of all types reiterate the adage that gross nutrient imbalance usually results in weight loss. Thus, all diets work for at least a short time. Severe restriction of protein, fats or carbohydrates independently or collectively will generally result in weight loss often placing the individual in some jeopardy in the process. Such diets can hardly become a way of life, however.

A lot of imagination and little medical science have gone into the popularized weight reduction regimens. The dietary variations available to the general public are limited only by the ability of publishers to meet apparently insatiable demands. Doctor Barbara Edelstein, on p. 695, reviews this present state of affairs in the dietary management of the obese subject.

Nutrition and Public Policy

It seems reasonable to assume that some physicians are confused by the outpouring of public policy recommendations on diets for Americans. Three major reports or dietary guidelines have been released within the past few years: U.S. Dietary Goals, a staff report of the U.S. Senate Select Committee on Nutrition and Human Needs (1977); Healthy People, The Surgeon General's Report on Health Promotion and Disease Prevention (1979); and Nutrition and Your Health, Dietary Guidelines for Americans, USDA/DHEW (1980). The first report proposed specific proportions of the macronutrients that should be consumed; the other two in more general terms, admonish Americans to eat less—or avoid too much fat, cholesterol, salt and sugar, and eat more fruits, vegetables, cereals and legumes. This is tantamount to establishing policy by employment of the incomplete comparative rather than the categorical imperative.

One difficulty with most of the governmental reports to the public (and directly or indirectly to the profession) about dietary change is the way the recommendations are worded. Eat less of this, more of that and avoid the other. The problem is that people are not all alike, and they do not eat out of a common bowl. Another difficulty is that of translating the specific recommendations into practical terms. Since people do not consciously select fatty acids, sugars, cholesterol and sodium, considerable educational effort would be required to bring about meaningful dietary changes where necessary. Qualitative advice is difficult to translate into meals and menus. One wonders why obdurate positions are being taken on diet and disease (or its prevention) in light of the lack of general agreement. Perhaps it is a manifestation of impatience, frustration, and conviction that present knowledge is adequate, or simply the feeling that the dietary habits of Americans are so bad that any changes would be welcome. "Do something" seems to be the prevailing attitude. The tendency has been to lump the therapeutic regimens for hypercholesteremias, hypertension and diabetes into one dietary mish mash and then tell the public to eat that way. Dr. Horwitz and Ms. Bauer in their paper on diabetes (p. 707) touch on this with recommendation that the U.S. Dietary Goals spell out a pretty good way for the diabetic patient to eat.

Hypertension has received a great deal of public attention because of its high prevalence. Most of the attention has been focused on the role of sodium in exacerbation of high blood pressure. Public policy pronouncements encouraging reduced consumption of sodium in order to "avoid" hypertension and the actual dietary management of the established hypertensive patient are two quite different concepts. One would never know by this reading the various public documents. Doctor Gifford provides us with the appropriate orientation in his presentation on hypertension on p. 699.

The AMA recently reviewed current relationships between nutrition and health and came away with its own approach to public health nutrition.[1]

> A common denominator of the various dietary guidelines proposed to modify the risks of chronic and degenerative diseases is the emphasis on restraint or moderation. Few would argue against the concept of "all things in moderation," though many would say that it is paltry advice in an era unsurpassed in advances in biomedical research. In time, when our knowledge of the relationships, if any, of specific food components to the development of chronic diseases reaches maturity, it may be feasible to make more refined recommendations. Until then, the AMA recommends that the American public give primary emphasis to the achievement and maintenance of the most desirable body weight and further recommends that this be accomplished through the combination of dietary control and exercise.
>
> This recommendation is considered the most appropriate for healthy people, but is also applicable to large numbers of Americans who are at greater risk for certain diseases and to those who must contend with specific dietary modifications

> instituted for the management of hypertension, diabetes, coronary heart disease, and other medical problems.

Weight control is often a first order of business in the management of hypertension, diabetes, coronary heart disease, and disorders of weight bearing joints, e.g., arthritis. Obviously, sodium restriction in hypertension and specific dietary management of the hyperlipidemias form important parts of treatment, but obesity is a common feature in degenerative diseases.

"Many problems associated with the 'usual American diet' and 'American food habits' reflect abandonment of the dictum of *moderation.*" The AMA statement emphasizes the great importance of the achievement and maintenance of the most desirable body weight through the combination of dietary control and exercise. Dietary control means moderation, restraint, variety, and good sense. *Moderation* in size and frequency of servings of foods, *restraint* in the use of any one food, beverage or condiment (salt), *variety* in the selection of foods and *good sense* in amounts of frivolous food consumed.

The development of good health habits should begin early in life. It is probably too late for the physician to be very influential once careless food habits have been firmly established or if obesity has persisted into late childhood. Ideally, the profession should be involved very early.

> Although responsibility for encouraging good food habits among children rests primarily with the parents, physicians should take advantage of every opportunity to educate their young patients.

AMA Concepts of Nutrition and Health ends with a final recommendation:

> The AMA recommends that the medical profession assume a more active role in teaching people how to achieve and maintain good health habits. This may require specific attention to behavioral patterns and attitudes about food and nutrition, physical fitness, smoking, the use of addictive drugs and alcohol, and the management of debilitating stress of life and work. Assisting patients to achieve their desirable weight and to develop appropriate patterns of exercise are among the most important goals.

Philip L. White, Sc.D.
Guest Editor

Director, Department of Foods and Nutrition
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Sex Education in Schools: How Much and by Whom?

Teenage pregnancies have become a major public health problem. In the last four years one birth in five in the U.S. was to a child-mother aged 11-18, with the peak occurring at the age of 16. Aside from the associated medical problems, adolescent pregnancies interrupt education and create major economic and social problems. The infant is usually brought up in a one-parent home and this one parent is frequently immature and not up to the task of rearing a child. The number of neglected or abused children raised by this age group is disproportionately high.

In a search for solutions to the problem, much has been made of the need to provide sex education for school children. Concluding that such instruction would provide an answer may be an illusion. In fact, sex education, if improperly presented, can increase the rate of pregnancies in the immature.

Unquestionably, there are some outstanding sex educators who do an effective, creditable job. But they are a mere handful. Confident about their own knowledge in this field, and how to teach it, they strenuously promote the inclusion of sex education in school curricula. What they seem to lack is the realization that there are other teachers, in fact the majority, who are totally unsuited to give instruction in this subject.

If a math or history teacher is a poor instructor, he may put his students to sleep or impart some misinformation that will either be forgotten or create little lasting injury. Few people end up on an analyst's couch or the obstetrician's table with problems related to Napoleon or Genghis Khan.

Some nine years ago, in one of New Haven's high schools, a course was initiated giving sex education in great detail. The instructor chose to use his own uncommon views, on methods of instruction. Subsequently, a comparison of the number of pregnancies in that school with another high school in the community of similar make-up showed that the rate of pregnancies was higher in the school which had provided the elaborate course.

That is not to say that sex education has no place in schools. But because of the vast differences in teachers' personalities and because no outsider sits in on the classrooms and hears how the topic is approached, three suggestions are made:

1) Sex education in schools should be provided by video material, film or tape, that can be previewed by educators and parents. Otherwise schools required to offer this type of education may assign the subject to individuals incapable of dealing with the subtlety and complexity of the topic. Prepared video material can be supplemented by appropriate written material which, in this particular field, is likely to be read.

2) The instruction should be provided separately for adolescent males and females. After a sex-related topic was presented in a local school system, a questionnaire was handed to the teenagers asking for their impressions and suggestions. A great majority of the girls stated that they would have preferred to have the topic presented in separate sessions. There is no need to force togetherness in this instance.

When separate sessions are held, questions tend to be more direct, pertinent and broader, and the discussion atmosphere is more relaxed. No matter how much effort is put into conjuring up a casual attitude about sex—that is, viewing it like any other subject, such as English or Latin—the facts are that the field has a strong emotional component and it will remain a touchy subject, particularly for the teenager, and often for the teacher as well.

3) Judging from reports of experiences in some communities in Minnesota and Maryland, a more effective way of reducing adolescent pregnancies is the one-to-one counseling session, run by knowledgeable personnel. The trouble with such programs is their cost, though it is certainly less than the high price of rearing unwanted infants.

Some feel that what is now offered in schools as sex education is a confused and jumbled mixture of science and pornography, part of it excellent, much of it unacceptably poor. While the evidence is lacking that intensive sex education in the schools could provide an answer to the vexing problem of adolescent pregnancies, efforts in this direction are worth pursuing with less fervor and cooler objectivity.

Hans H. Neumann, M.D.
Medical Director
New Haven Department of Health

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(continued from p. 747)

Online, 1980-. (Data base searchable through the AMA Library).

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Modern Approaches to the Chemoprophylaxis of Infection in Abdominal Surgery

ALDO L. BELLUCCI, M.D. AND RICHARD QUINTILIANI, M.D.

Introduction

Probably the greatest use of antibiotics occurs in the area of chemoprophylaxis, perhaps because physicians, like everyone else, want life to be pasteurized and risk free. Although this certainly seems a worthy goal, such extensive use often becomes abuse. Excessive attempts to produce a sanitized life, particularly with the administration of potentially toxic antibiotics, may in many instances create more harm than good. Ironically, one of the major problems with the use of prophylactic antibiotics is that they may result in infections far worse than the ones they tried to prevent. It is amazing how often one hears about the patient who may have been saved by preventive antibiotics, but how seldom one learns about persons who have been harmed by them, either from adverse drug reactions, from suprainfections, or from both.

We often forget that there are other safe and more effective ways to prevent infections than by administering antibiotics. It has been said that for prevention of diarrhea and intestinal infections it is probably more important to have a plumber in one's city block than to have a physician. The worker who shovels fluoride into the city reservoir probably prevents more cavities than all the dentists in this country. Certainly the best line of defense against domestic insect pests such as lice is merely good personal hygiene. We often forget that host defenses play an important role against infections and that without them almost all approaches will fail. Normal, healthy persons rarely need chemoprophylaxis unless they are exposed to massive sustained bacterial invasion, whereas neutropenic patients often succumb to minimal transient bacteremia from their own intestinal tract.

Assessment of the effects of antibiotics in surgery is difficult, for this type of drug is only one of many factors that can influence recovery. Antibiotics probably play a minor role in preventing postoperative infections compared to that of the skills of the surgeon who removes dead tissue and blood clots, stops bleeding and provides adequate drainage; or to that of the activities of a well-trained hospital epidemiologist who maintains proper infection control policies.

In the decades of antibiotic usage, answers have been slow to emerge as to what clinical situations are best for chemoprophylaxis, mainly because of the absence of adequate double-blind, prospective randomized studies in this area. Consequently, the debate over prophylactic antibiotics has become so polarized that it is hard to find any trustworthy answers. This article represents an effort to bring some order to this confusing subject.

In the area of prophylactic antibiotics, no aphorism has been more firmly established than the one often stated by Dr. Louis Weinstein: "Antibiotics prevent infection best when they are directed against a single pathogen; they prevent infection least, and may even do harm, when they are directed against multiple pathogens with varying antimicrobial susceptibility patterns." This generalization can be further refined: the shorter the time needed for prophylaxis, the better the protection; the longer the time needed for prophylaxis, the worse the protection. The results of chemoprophylaxis will depend on how closely the particular clinical situation coincides with these two variables. In this article we direct our attention to the use of antibiotics to prevent infection in intra-abdominal surgery.

Antibiotic Prophylaxis in Biliary Tract Surgery

Antibiotic prophylaxis before biliary surgery appears justified at least for patients with increased risk of infection (patients over 70 years of age and those with acute cholecystitis, obstructive jaundice, or common duct stone), especially since the usual pathogens are few in number. In reviews of bacteremia in association with biliary tract surgery, about 85% of the time the invasive organisms are either *Escherichia coli* or *Klebsiella pneumoniae,*[1] organisms that are usually susceptible to cephalosporins. For greater coverage of the operative period, some surgeons prefer the combination of an aminoglycoside and ampicillin, but in studies comparing a cephalosporin alone versus the combination therapy, there were no differences found in the amount of protection.[2,3]

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Antibiotic Prophylaxis in Intestinal and Genital Tract Surgery

When attempting to avoid infection from multiple pathogens with variable susceptibility patterns, as those that occur in the intestinal tract, one must consider length of exposure to be the crucial determinant of success or failure. If the bacteremia is transient, as that which usually accompanies diagnostic procedures such as sigmoidoscopy, protection can be obtained against endocarditis in high-risk patients by the administration of an aminoglycoside (e.g., gentamicin, tobramycin, or amikacin) and a penicillin derivative (e.g., ampicillin). These aminoglycosides are usually active in vitro against practically all important bacterial pathogens except anaerobes and streptococci. By adding a penicillin derivative, one achieves protection against streptococci and the anaerobes except from *Bacteroides fragilis.*

Although the combination of an aminoglycoside and a penicillin or ampicillin achieves excellent coverage against gram-negative bacteria, in bacterial endocarditis prophylaxis the synergistic effect of this antibiotic combination against the enterococci (e.g., *Streptococcus faecalis)* is most important, since the enterococcus is the organism that most often produces endocarditis following genitourinary tract and gastrointestinal tract surgery or instrumentation, and since bacteremias with gram-negative bacteria uncommonly produce this type of infection. In keeping with these views, the American Heart Association[4] now recommends, for prophylaxis against endocarditis in high-risk patients undergoing gastrointestinal and genital tract surgery and instrumentation, the administration of aqueous crystalline penicillin G, 2 million units (intramuscularly or intravenously), plus gentamicin, 1.5 mg/kg (not to exceed 80 mg) (intramuscularly or intravenously), or streptomycin, 1 mg (intramuscularly), 30 minutes to 1 hour prior to the procedure, followed by two additional doses (gentamicin every 8 hours or streptomycin every 12 hours). For patients who are allergic to penicillin, the regimen is vancomycin, 1 gm intravenously, plus streptomycin, 1 gm intramuscularly. It also recommends that normal individuals and most cardiac patients do not require a prophylactic antibiotic for diagnositc procedures such as percutaneous liver biopsy, proctoscopy, sigmoidoscopy, barium enema, pelvic examination, dilatation and curettage of the uterus, and the uncomplicated insertion or removal of intrauterine devices. In especially high-risk patients such as those with prosthetic heart valves, however, the American Heart Association[4] supports the use of prophylactic antibiotics in these procedures.

While only high-risk patients usually require antibiotic prophylaxis for transient bacteremia, it has become widely accepted that all individuals undergoing certain gastrointestinal and gynecologic operations associated with significant bacterial contamination of the peritoneal cavity warrant protection against intra-abdominal wound sepsis. Typical operative procedures that fall into this category are resections of the colon, terminal ileums, necrotic bowel and vaginal hysterectomies. Since the moment of tissue contamination usually occurs in the intraoperative period, antibiotics can be administered shortly before or after the lodgment of bacteria when experimental studies[5] show the possibility of protection to be the best.

Traumatic wounds to the abdomen should fall into the same category since these patients usually receive medical attention shortly after the injury. There is, however, no general agreement on which antibiotic(s) or which route (systemic vs oral) or administration provides the best results. Unlike bacterial endocarditis prophylaxis for gastrointestinal and genitourinary procedures in which the coverage is aimed at enterococci, prophylaxis against intra-abdominal sepsis requires broad coverage since the usual pathogens responsible for infection in this clinical setting are gram-negative enteric bacteria.

Colorectal surgery continues to be particularly troublesome because it involves entry into areas heavily colonized with both aerobic and anaerobic bacteria and, even with the most scrupulous technique, postoperative infections are high (20-50%).[6] Many studies have been published describing various ways to reduce these prohibitively high infection rates.

On reviewing these reports from the early 1960's to the present, two approaches have usually been employed to significantly reduce postoperative infections: (1) *the administration of antibiotics by the oral route* preoperatively to reduce the total number of bacteria in the intestinal contents that may spill into the peritoneal cavity permitting host defenses to resist infection more easily; and (2) *the injection of antibiotics intramuscularly or intravenously* immediately before surgery so that effective levels are attained in tissue and in blood at the moment of maximal bacterial contamination or bacteremia (i.e., the intraoperative period). Both approaches include preoperative mechanical preparation (liquid diet, cathartics, enema) of the bowel.

The first approach usually employs two different antibiotics, of which one (e.g., neomycin, kanamycin) has significant microbiologic activity against aerobic enterobacteriaceae (e.g., E. coli, Proteus spp, *Klebsiella pneumoniae),* while the other one (e.g., erythromycin, metronidazole) has appreciable microbiologic activity against anaerobic bacteria, particularly *Bacteroides fragilis.* Neomycin and kanamycin, like all aminoglycosides, are not absorbed orally to a significant extent whereas erythromycin and metronidazole are well absorbed by this route. The usual policy is, however, to administer the erythromycin or the metronidazole on the day(s) before but not the day of surgery, which results in minimal, if any, systemic levels at the time of the operation. The timing policy with the second or systemic antibiotic approach is entirely opposite to the first approach in that the drug is most often given on the day of the operation, usually at the start of the procedure in the operating room to achieve maximal systemic levels during the operative period. It is tempting to speculate that a combination of these two approaches would provide the best protection against infection yet we are unaware of any published studies that test this hypothesis.

Although most surgeons agree mechanical preparation of the bowel facilitates surgery by reducing the quantity of fecal material, the concentration of bacteria per gram of feces remains the same.[7] Evidence of the protective benefits of antibiotics in colorectal surgery emerge when one compares the infection rate with the mechanical bowel preparation alone with mechanical preparation and oral or systemic antibiotics.

Washington et al[8] in a prospective randomized double-blind study of postoperative wound infections following colorectal surgery noted that the rate was 5% in the group who received a 48-hour preoperative regimen of oral neomycin and tetracycline and purgatives, while the rate was 43% in the patients who were given mechanical bowel cleansing alone or with neomycin. In addition to supporting the benefits of oral antibiotics, this study provides further support to the important role of anaerobes in colorectal surgery, for neomycin exhibits essentially no activity against these organisms. The importance of using a drug with antianaerobic activity is also shown in another study[9] in which the investigators tabulated the wound infection in patients undergoing colorectal surgery who received either oral kanamycin alone or the combination of oral kanamycin and erythromycin, the infection rate was 41% in the former group compared to 8% in the latter group.

A large multicenter trial in Great Britain[10] compared the efficacy of mechanical bowel preparation alone to a combination of neomycin and metronidazole orally for 2 days before surgery. The antibiotic approach resulted in significant reduction of wound sepsis, septicemia, anastamotic dehiscence, total patients with postoperative sepsis, and the mean length of hospital stay. In the United States, metronidazole has, however, no approval for usage as a prophylactic drug prior to bowel surgery.

After a brief prospective study comparing mechanical preparation alone to mechanical cleansing plus neomycin and erythromycin, Nichols et al[11] detected a clear difference in results with no septic complications in the antibiotic group versus 30% in the controls. During a two year period, they administered the neomycin-erythromycin combination (1 gm of each drug by mouth at 1 p.m., 2 p.m. and 10 p.m.) on the day before colorectal surgery to 174 patients and observed a wound infection rate of less than 3%. In a large Veterans Administration Cooperative Study[12] a similar antibiotic approach was compared to mechanical preparation alone or to a mechanical preparation plus preoperative dose of cephalothin. In the patients treated with oral antibiotics, there was a significant reduction (30% in control versus 6% in treated group) in the total number of septic patients, wound infections, intra-abdominal septic complications (abscess or peritonitis) and bacteremia. The wound exudates of infected patients contained a mixed aerobic-anaerobic flora, predominately *Escherichia coli* and *Bacteroides fragilis.* The oral approach has a profound effect on the quantity of organisms per gram of feces, usually reducing the number of bacteria by 4-5 logs.[13] Surprisingly, the patients who received cephalothin had infection rates comparable with the control group. It is possible that the poor results with cephalothin in this study were due to its rapid elimination from tissue owing to its very short serum half-life (30 minutes). As will be mentioned below, cephalosporins with a longer serum half-life, like cephaloridine and cefazolin, have significantly reduced infection complications in intra-abdominal surgery.

Instead of two different oral drugs, a study using a single agent (doxycycline) with microbiologic activity against both aerobic and anaerobic bacteria has also been found effective in reducing infection following colorectal surgery.[14] In this trial 200 mg of doxycycline was given orally 4-6 hours before surgery and then 100 mg daily for 5 days resulting in a wound infection rate of only 8.6% compared to 41.6% in the control group.

Systemic antibiotics have been used with variable results but the majority of studies support their protective effects. For instance in a well-controlled study,[15] cephaloridine 1 gm intramuscularly on call for surgery followed by 1 gm 5 and 12 hours thereafter substantially reduced postoperative infections (30% in controls; 7.4% in treated group). On a theoretical basis, a cephamycin antibiotic, like cefoxitin, should be even more protective than a cephalosporin antibiotic, since compared to the latter, cefoxitin has enhanced activity against gram-negative bacteria, including *Bacteroides fragilis.* Comparing oral kanamycin (3 grams for 3 days) and metronidazole (1.2 grams for 2 days) before operating to 3 doses of kanamycin and metronidazole by injection (first dose given just before surgery and the next 2 doses at 12 hour intervals after surgery), Keighley et al[16] found a 6.5% rate of postoperative sepsis in the patients receiving parenteral drugs compared to 36% in those receiving oral agents. The reason for high infection rates in the group treated with a seemingly appropriate drug remains unknown. In addition 6 of 47 patients on the oral regimen developed pseudomembranous colitis versus 1 of 46 on systemic antibiotics.

Based on studies of the type mentioned above, the following statements appear valid in reducing infection following colorectal operations:

1. When either oral or systemic antibiotics are given along with mechanical bowel preparation, the frequency of infection is reduced in comparison to the use of mechanical bowel preparation alone.

2. The combination of oral neomycin and erythromycin given in three separate 1 gm doses on the day before surgery achieves significant protection against infection. Whether the addition of a parenteral antibiotic(s) (e.g., cefoxitin or a long-acting cephalosporin, like cefazolin) to the oral regimen would further reduce infection remains unanswered, but should be studied.
3. Since either the single dose or several doses of a systemic antibiotic or the one day preoperative oral antibiotics reduce postoperative infections, it seems inappropriate to continue them long, if at all, after the intraoperative period. Certainly to avoid adverse drug reactions, suprainfections and cost, one should limit the number of doses.

A suggested regimen to avoid infection following colorectal surgery is given in Table 1.

Table 1

RECOMMENDED APPROACH TO PREVENT INFECTION FOLLOWING COLORECTAL SURGERY

Day 1	Low residue diet. Bisacodyl, 1 capsule orally at 6:00 p.m.
Day 2	Continue low residue diet. Magnesium sulfate, 30 ml, 50% solution (15 grams) orally at 10:00 a.m., 2:00 p.m. and 6:00 p.m. Saline enemas in evening until return clear.
Day 3	Clear liquid diet. Supplemental intravenous fluids as needed. Magnesium sulfate in dose as above at 10:00 a.m. and 2:00 p.m. No enemas. Neomycin 1 gram and erythromycin base 1 gram orally at 1:00 p.m., 2:00 p.m. and 11:00 p.m.
Day 4	Operation scheduled at 8:00 a.m. Optional: Immediately prior to the surgical procedure in the operating room, give patient cefoxitin 2 grams intravenously and repeat this dose twice at 6 and 12 hours after the first dose and then discontinue the antibiotic.

Most gastroduodenal surgery has a much lower rate of infection than colorectal surgery, probably because of relatively sparse resident flora in the regimen of the alimentary tract. Nevertheless, in patients with obstructive disease in this area or with cancer of the stomach, prophylactic antibiotics may be of benefit since in these situations the quantity of bacteria may be appreciably higher.

There should be no need for antibiotic prophylaxis in the usual abdominal hysterectomy or cesarean sections since the extent of bacterial contamination of the peritoneal cavity should be minimal unless the intestines are inadvertently entered.

There appears to be no justification for even single-dose antibiotic prophylaxis of primary wound sepsis after clean operations since the infection rate in procedures of this type has always been very low in the presence of proper surgical technique.

Summary

In summary, the decision to intervene or not to intervene with an antibiotic for the possible prevention of an infection must be based on several considerations. First, if natural defense mechanisms against infection are normal, then prophylactic antibiotics are seldom needed unless the extent of contamination is massive. Second, in most of the well-established and successful applications of antibiotic prophylaxis, the drug is aimed with precision at specific organisms. Third, protection is most evident when the prophylactic antibiotic is introduced shortly before or after the time of maximum tissue contamination. Finally, the inconvenience, risk and cost associated with the protection technique must be compared with the inconvenience, risk and cost associated with the infection to be avoided.

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Fine Needle Aspiration Biopsy of the Thyroid: An Initial Clinical Evaluation

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A growing clinical literature has developed with respect to the use of fine needle aspiration biopsy of the thyroid gland in the differential diagnosis of thyroid malignancy in patients with goiter and thyroid nodules.[1,2,3] The ability to examine directly thyroid cytology, including the cytology of clinically relevant thyroid nodules, is appealing. The technique of aspiration biopsy requires technical proficiency in sample collection and a competent cyto-pathologic laboratory for proper interpretation.[3] Despite a significant literature describing thyroid fine needle aspiration biopsy and interpretation, the method has not been utilized by the majority of physicians and surgeons, who continue to apply a variety of indirect means to determine which patients with goiters or thyroid nodules require surgical excisional biopsy.[4] The present article outlines an initial experience with fine needle aspiration biopsy of the thyroid gland at Hartford Hospital. Twenty-five patients with a variety of clinical thyroid disorders were evaluated. This experience provides a useful perspective of the role of aspiration biopsy of the thyroid in the differential diagnosis of thyroid disorders as an adjunct to conventional noninvasive thyroid studies.

Technique

All thyroid fine needle aspiration biopsies were performed on an out-patient basis. Local anesthesia with 1% Xylocaine was employed. After sterilization with Betadine and alcohol, a disposable 22 gauge, 1½ inch needle was introduced percutaneously, vertically into the thyroid gland in the case of diffuse goiters, or into the thyroid nodule to be biopsied. The nodule was fixed by the left hand while negative pressure was applied by the right hand through an attached 3 ml. disposable plastic syringe. Three to six passes through the central portion of the nodule or the thyroid gland were used to obtain adequate material for cytologic evaluation. Negative aspiration pressure was released before the needle was removed. After removal the syringe was disconnected from the needle and reattached after filling with air, in order to express the aspirated material contained in the needle onto a frosted cytologic slide. A smooth glass slide does not adequately retain aspirated material during fixation. The drop of material was then smeared along the slide with the flat edge of the needle and placed in an ether-alcohol "Pap" bottle for fixation prior to conventional hematoxylin-eosin staining and cytologic interpretation. An optimal thyroid aspiration sample is orange in color and non-hemorrhagic, approximately 0.1 ml. in volume and contains fine threads of aspirated tissue which are easily grossly identified. A second aspiration biopsy was performed if the initial sample was either inadequate or excessively hemorrhagic, or if a second nodule of clinical interest required independent cytologic assessment.

Complications

No significant complications were encountered. All patients tolerated the procedure well. Minimal transient discomfort with deep penetration was described. Several hemorrhagic samples were obtained but intrathyroidal hemorrhage was easily controlled by local pressure and was never a clinically significant complication of the procedure. No patients declined repeat aspiration when clinically indicated. Four patients (15%) required reaspiration on a second occasion because of inadequate cellular material on the initial sample.

Results

The results are summarized in Table 1. Twenty-five patients were evaluated. No patients with a functional nodule by thyroid Tc-99M or I-123 scan were studied. No patients who had nodules that were felt to require

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surgical excisional biopsy because of standard clinical criteria suggesting thyroid carcinoma were studied.

Seven patients (1-7) with diffuse goiters which failed to suppress adequately following thyroid suppressive therapy of up to seven years' duration were studied. One patient (patient 1) with residual diffuse goiter had a previous Vim-Silverman cutting needle biopsy and open surgical biopsy attempted, but inadequate material was obtained for interpretation. A highly satisfactory cytologic fine needle aspiration was obtained in this patient.

Thirteen (8-20) patients had solitary thyroid nodules that were hypofunctional by scan. Ten patients had received thyroid suppressive therapy for between three to eight months without significant change in nodule size. Three patients were biopsied at the time of initial evaluation. Adequate samples were obtained from all patients with solitary nodules. The nodules ranged from 2 to 5 cm. in size. All nodules showed normal thyroid follicular cytology or were cystic at the time of aspiration. In one patient (patient 8) with a clinically previously unsuspected cystic lesion, the nodule was successfully completely aspirated and clinical recurrence has not occurred with continuation of thyroid suppression.

One patient (patient 13) who developed a thyroid nodule during pregnancy was studied. Pregnancy contra-indicated conventional radioisotope evaluation of the thyroid nodule. The cytologic aspirate revealed normal thyroid follicular epithelium and suppressive thyroid therapy was continued during pregnancy and during subsequent nursing. One patient (patient 23) with relative to absolute contra-indications to general anesthesia and excisional surgical biopsy was studied, and on the basis of benign aspiration cytology, continued on suppressive treatment.

Five patients had a multinodular goiter in which a dominant hypofunctional nodule led to concern with respect to coexistent thyroid carcinoma. One of the four patients (patient 22) was demonstrated by cytologic aspiration to have metastatic carcinoma of the lung. This patient has had previous carcinoma of the lung treated one year previously by lobectomy. Detailed post-operative re-evaluation two months prior to thyroid aspiration biopsy, including bronchoscopy and multiple bronchial biopsies, had failed to demonstrate recurrence.

Discussion

The present experience is similar to that previously reported by several groups.[1,2,3,5] The thyroid aspiration cytologic technique is simple, well tolerated and adds significantly to the overall assessment of thyroid pathology in patients with diffuse goiter, solitary thyroid nodules and multinodular goiters. The procedure supplements conventional noninvasive thyroid evaluation by isotopic and ultrasound techniques, as well as by evaluation of thyroid function and thyroid antibody status. No evidence of seeding of tumor in the needle track was noted in the single patient with carcinoma. The extensive literature does not document any such complication in fine needle biopsy.[1,2,3]

Familiarity with fine needle aspiration of other organs unquestionably is a help in interpreting thyroid material. The cytopathologist who has dealt principally with classical Papanicolaou gynecological material will find a different orientation and approach more akin to surgical pathology necessary. The usage of ground-glass slides for cellular retention and immediate alcohol fixation is essential. The only exception is in the case of possible lymphoma. In this situation, at least one smear should be air dried and stained by Wright-Giemsa stains. Material fixed by 95% alcohol is best stained by hematoxylin and eosin method. The Papanicolaou stain variants are unnecessary.

Nuclear morphology is altered in well differentiated papillary carcinomas with a characteristic vacuolated nucleus, "Little Orphan Annie Eyes," effect often encountered. Groupings of cells with a papillary configuration as well as psammoma bodies are frequent. Less differentiated carcinomas, both papillary and follicular, demonstrate typical cytologic criteria of malignancy with hyperchromatism, coarse chromatin, prominent nucleoli as well as nuclear enlargement and irregularity. Thickening of the nuclear membrane and variations of its inner margin may be encountered. It is the well differentiated follicular carcinomas which present problems just as they so often do in histologic diagnosis. Vascular and capsular invasion cannot be observed from the cytologic method. Fortunately these cases are less frequently encountered than the papillary lesions and where suspected surgical excision and examination by many permanent histologic sections is usually required for diagnosis.

Thus fine needle aspiration biopsy neither replaces open excisional biopsy or conventional thyroid assessment, but functions best to establish a positive diagnosis of thyroid carcinoma. A negative cytologic aspiration does not adequately exclude thyroid carcinoma, particularly well differentiated follicular carcinoma of the thyroid. In combination with other diagnostic criteria, however, fine needle thyroid aspiration provides a valuable additional diagnostic modality, narrows the probability of error in clinical thyroid nodule assessment, and in this series has permitted continuation of medical therapy where thyroid surgery primarily for diagnostic means would otherwise have been necessary. In patients with thyroid nodules who are pregnant or nursing, in whom isotopic thyroid scans are contra-indicated, and in patients with contra-indications to general anesthesia, fine needle aspiration is of unique value. The initial experience with fine needle aspiration biopsy of the thyroid at Hartford Hospital recommends its further use in the differential diagnosis of focal and generalized thyroid disorders.

TABLE 1 - CLINICAL SUMMARY

Patient	*Clinical*	*Scan*	*Functional Status*	*Thyroid Antibody*	*Response to Suppression*	*Fine Needle Cytology*
DIFFUSE GOITER						
1. 35F	Diffuse goiter, 100 Gm.	N.D.	Euthyroid	+1:640	No suppression 7 years	BFE lymphocytes
2. 43M	Diffuse goiter, 50 Gm.	Diffuse goiter	Euthyroid	+1:40,000	Residual left lobe enlargement, 10 mo.	BFE
3. 31F	Diffuse goiter, 60 Gm.	N.D.	T4 5.6 mg/dl. TSH 20 uU/ml.	+1:20,000	50% decrease 3 years	BFE lymphocytes
4. 40F	Diffuse goiter, 45 Gm.	N.D.	Euthyroid	Neg	No suppression 6 years	BFE
5. 61F	Diffuse goiter, 200 Gm.	Diffuse goiter	Euthyroid	Neg	No suppression 1½ years	BFE
6. 31F	Diffuse goiter, 60 Gm.	N.D.	Euthyroid	Neg	15 Gm residual gland, 3 years	BFE lymphocytes
7. 45F	Diffuse goiter, 80 Gm.	Hypofunctional nodule	Euthyroid	+1:6400	Initial evaluation	BFE
SOLITARY THYROID NODULE						
8 51F	25 mm. nodule isthmus	Hypofunctional nodule	Euthyroid	N.D.	No suppression 7 months	3 ml. clear fluid
9. 40M	40 mm. nodule right lobe	Hypofunctional nodule	Euthyroid	+1:5000	No suppression 10 months	BFE
10. 47M	30 mm. nodule left lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 3 years	BFE hemosiderin
11. 43M	20mm. nodule right lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 3 months	BFE hemosiderin
12. 20F	30 mm.nodule left lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 3 months	BFE highly cellular
13. 29F	40 mm. nodule left lobe	N.D. (Pregnant)	Euthyroid	N.D.	No suppression 5 months	BFE
14. 31F	40 mm. nodule left lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 3 months	BFE
15. 46F	50 mm. nodule left lobe	Multinodular hypofunctional nodule, left lobe	Euthyroid	N.D.	No suppression 2 months	BFE
16. 43F	20 mm. nodule right lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 3 months	BFE
17. 77F	40 mm. nodule left lobe	Hypofunctional nodule	Euthyroid	N.D.	No suppression 5 years	BFE
18. 24F	10 mm. nodule right lobe	Hypofunctional nodule	Euthyroid	N.D.	Initial evaluation	BFE
19. 47F	35 mm. nodule left lobe	Hypofunctional nodule	Euthyroid	N.D.	Initial evaluation	BFE 2 ml. cyst fluid
20. 45F	25 mm. nodule right lobe	Hypofunctional nodule	Euthyroid	+1:25,000	Initial evaluation	BFE
MULTINODULAR GOITER						
21. 65M	Multinodular dominant 50 mm. nodule	Multinodular hypofunctional nodule	Euthyroid	N.D.	No suppression 3 years	BFE
22. 64F	Multinodular dominant 50 mm. nodule	Multinodular hypofunctional nodule	Euthyroid	+1:1280	No suppression 9 months	Metastatic carcinoma lung
23. 62M	Multinodular dominant 50 mm. nodule	Multinodular hypofunctional nodule	Euthyroid	Neg	No suppression 2 years	BFE
24. 58F	Multinodular dominant 50 mm. nodule	Multinodular hypofunctional nodule	Euthyroid	Neg	No suppression 1½ years	BFE hemosiderin
25. 43F	Multinodular dominant 50 mm. nodule	Multinodular hypofunctional nodule	Euthyroid	N.D.	No suppression 6 years	BFE 10 ml. cyst fluid

N.D.	Not done
T4	Serum Thyroxine (4.5-12.0 mcg/dl.)
TSH	Serum Thyroid Stimulating Hormone (0-7.5 uU/ml.)
BFE	Benign follicular epithelium

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The Recognition and Management of the Dangerous Patient

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The dangerous or potentially violent patient presents a grave threat to the physician and his staff either in the office or in the Emergency Room. The management of the dangerous patient is more complex than the management of the suicidal patient, which is the other basic type of psychiatric emergency that the author has discussed elsewhere.[1] This results from the great variety of dangerous situations which confront the physician. In addition, the physician is frequently required to predict future dangerousness or degree of instability for treatment or in relation to medical/legal issues, (eg. involuntary hospitalization of disturbed individuals). Finally, the physician must be able to recognize and manage the potentially violent patient in order to protect himself and others from harm.

The Recognition of Dangerousness

Unfortunately, physicians rarely have either training or experience in recognizing or managing dangerous patients. We are taught to deal with illness, and dangerousness is not an inherent part of any psychiatric illness. *Dangerous* is an adjective which defines a particular type of behavior. It refers to the likelihood that an aggressive, destructive and socially unacceptable act will occur in the reasonably foreseeable future, with a high probability of substantial injury. As Stone has pointed out, "Dangerousness like beauty is in the eye of the beholder;" it can only be defined by one person in relation to another.[2] Thus, a patient may be dangerous at home in relation to his wife in a setting of violent discord, but he is not necessarily dangerous in relation to you in your office.

The physician frequently is in a double-bind when attempting to assess dangerousness in relation to legal issues. The judicial system expects crystal-ball accuracy from us. If a person is diagnosed as dangerous by his physician, then he can be confined involuntarily to prevent the dangerous act from occurring. It is interesting that the Law disdains preventive detention to prevent crime, but will allow it for the emotionally ill. State law usually requires that a prediction of dangerousness be in the realm of 90% accuracy ("beyond reasonable doubt"); in other civil proceedings, it does not require this exactitude. Finally, the legal profession believes civil commitment or involuntary hospitalization is to prevent injury such as suicide, homicide or assault. The medical profession is more concerned with appropriate treatment. We only wish to hospitalize a patient if he is suffering from an illness that we can treat.

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A number of recent articles in the legal literature have criticized doctors for poor accuracy in the prediction of dangerousness. This supposedly has led to our unnecessarily hospitalizing thousands of people every year. Because physicians are concerned about treatment and about preventing harm to the patient and others, we frequently do tend to be conservative in this area. The problem is that when we determine that a patient is dangerous and hospitalize the patient involuntarily, there is little opportunity to verify the accuracy of the prediction since the patient is then institutionalized.

A recent occurrence has confounded this situation to an even greater degree. Based on a 1976 decision of the California Superior Court (Tarasoff vs. the Regents of the University of California) the physician is now liable for failure to warn the intended victim when a patient informs him that he plans to harm someone.[3] This duty is considered to supersede the requirement of confidentiality which has been a basic tenet of the physician/patient relationship. Now the doctor is required to determine with even greater accuracy whether or not the patient is actually intent on harming someone, for his failure to warn an intended victim could result in legal consequences.

The Management of Dangerousness

The management of the dangerous patient can be divided into four steps: 1) the prediction of the degree of dangerousness; 2) the assessment of urgency; 3) the diagnosis of the cause; and 4) the intervention and treatment.

Step 1: The Prediction of the Degree of Dangerousness

While no particular psychiatric diagnosis necessarily connotes dangerousness, certain situations have a greater likelihood for the occurrence of violent acts. Patients suffering from paranoid schizophrenia or having paranoid symptoms as well as those under the influence of drugs such as phencyclidine, amphetamines or alcohol are more likely to behave violently. Perhaps the single most important factor is a previous history of violent behavior. Once a patient has acted violently towards others in the past, there is much greater likelihood that he will behave in a violent manner again. The triad of fire setting, enuresis and cruelty to animals occurring in the patient's past was thought to be predictive of potential violence. The validity of this triad has not been proven; however, a history of truancy, fighting in school and temper tantrums has been found to correlate with violent acts later in life.

Other exceedingly important factors include a history of family friction, (especially with abuse of the patient,) previous threats of violence, a penchant for weapons and the patient's inability to experience pleasure or to become involved in meaningful activities. The patient's perspective of other human beings is also significant. If the patient is able to dehumanize others so that they are seen merely as a hindrance or as things which must be gotten rid of, then there is an increased likelihood that violence will occur. This dehumanization factor has been observed with increasing frequency among juvenile perpetrators of various kinds of street crime.

It is possible to accurately predict violent behavior in the Emergency Room. Monahan has demonstrated that the time frame is crucial however.[4] The shorter the period of time between your prediction and the time when you expect the violent act to occur, the greater the validity. In addition, the context or setting of the prediction and the place where you expect the behavior to occur must be the same. In other words, we can accurately determine that a patient whose behavior we observe in the Emergency Room may become violent in the Emergency Room within a relatively short period of time. It is more difficult to predict whether the same patient will be violent in the community two weeks from now.

The following checklist of factors developed by Skodol and Karasu in a study of 62 violent Emergency Room patients helps to recognize and predict the degree of dangerousness of the patient:[5]

1. The amount of violent intention expressed by the patient.
2. The openness of violent thoughts or threats.
3. The presence or absence of substantial conflict experienced by the patient concerning the violent impulse.
4. The patient's understanding of the situation and the apparent degree of his ability to control impulses.
5. The specificity and the availability of the actual or intended victim.
6. Whether the impulse has been confined to thinking or has been acted out.
7. The apparent premeditated or chronic nature of the impulse as contrasted to its spontaneity or acuteness.
8. The presence of psychosis, organicity or intoxicants in the patient.

Keeping these guidelines in mind, you must gather as much information as possible from the patient and from family members or other available parties. This must be done skillfully so as not to further aggravate an already upset patient. You must be flexible rather than rigid in your response to the patient. The performance of a formal physical, neurological or mental status examination may have to be delayed until the patient is willing to cooperate. The higher the number of positive responses to the various prediction factors, the greater the degree of dangerousness of the patient. Direct numerical correlations between these predictions and the likelihood of violent behavior have yet to be determined. However, using your clinical judgement in relation to these factors, you should assess whether you consider the patient to be minimally, moderately or severely dangerous.

Step 2. The Assessment of Urgency

While considering the degree of dangerousness, you must also determine the level of urgency. How much time do you have in which to diagnose the cause and to intervene? Tupin has differentiated three levels of urgency in relation to the dangerous patient:[6] 1) the acute or actively violent patient; 2) the subacute or agitated patient; and 3) the chronic or potentially violent patient. The actively violent patient is intent on harming you or someone else; he frequently is psychotic; he may have a weapon. The subacute patient may be agitated, restless and threatening. Although he may have already attempted to harm someone slightly, he has not yet fully lost control and is capable of reasoning. The potentially violent patient may have done harm in the past, but now either is actively seeking your help or at least is willing and able to cooperate with you. Your determination of the level of urgency along with your prediction of the degree of dangerousness will dictate the time frame for making the diagnosis and the type of intervention you must use. In the case of the acute or subacute patient, you must intervene immediately; with the chronic patient you usually have adequate time to do a complete diagnostic evaluation to determine the etiology of the dangerous behavior.

Step 3. Diagnosis of the Cause

Patients may become dangerous because they are suffering from psychiatric illnesses, such as paranoid schizophrenia or acute mania. They may become dangerous because of social or cultural factors in their lives, such as various kinds of deprivation or child abuse. They may become dangerous because of biological factors such as brain trauma and injury. Various genetic disorders, such as the XYY chromosomal abnormality, in recent years have been linked to criminal behavior. Finally, external factors such as alcohol and drug abuse may account for dangerous situations.

Assuming that you have the time to adequately evaluate the patient, you obviously must obtain as complete a history as possible, using additional informants if available. You should perform a complete physical, neurologic and mental status exam. Based on your initial impression, you then must obtain appropriate laboratory and diagnostic studies. Unfortunately, because of the nature of these situations, you rarely have the luxury of performing a complete diagnostic evaluation before having to commence at least part of your intervention.

Step 4. The Intervention and Treatment

Any intervention you use must be characterized by three factors. It must be safe; it must be effective and it must be flexible. *Safety* means that neither you, the staff nor the patient will be harmed when you intervene. It also means that certain drugs cannot be used to treat patients who have ingested particular substances. *Effective* means that you are well versed in the use of the particular intervention and relatively certain that it will work in this situation. *Flexible* means that the intervention can be applied equally well in different kinds of dangerous situations, perhaps with the help of different staff members.

The types of interventions available to you are verbal, physical and pharmacologic. The particular ones you use will depend on the urgency and severity of the situation. *Verbal interventions* are not useful with acutely dangerous patients who are out of control and who will not respond to empathetic or supportive statements. They are frequently helpful with the subacute or potentially violent patient. You must let the patient know that you are calm and in control of the situation. You must treat the patient with dignity, but with the reassurance of firmness. You must have adequate time to deal with the patient. To attempt to hurry a patient at this moment may lead to an increased potential for violent behavior. A denial of the seriousness of the problem to the patient may also increase the potential for violence. To the extent that you can communicate to the patient that you are not afraid but that you are willing and desirous of helping him deal with his problems, this may diffuse the tension of the situation. It is important for the patient to understand that he may *say* whatever he wishes; he may not *do* whatever he wishes. For some patients it is frequently important that the professionals attempting to help them be of the same sex, and this should be taken into consideration.

Physical intervention or environmental manipulations are frequently the most safe, effective and flexible when dealing with the severely dangerous patient; they frequently are not necessary with the other types of patients. These include separating the patient from the object of his anger, using seclusion rooms or various types of physical restraints. If the need for physical control exists, then you must have adequate staff support before approaching the patient. In such cases it is imperative that you have one staff member to control each limb and a fifth to apply restraints or give medication in order for this intervention to be safe. If possible, you should rehearse your strategies before using them, so each team member knows exactly what to do. While in some cases the use of a mattress as a shield may help protect you, especially if the patient is armed with a weapon, the use of the five-member team for restraint is frequently most effective.

Pharmacologic interventions can be used effectively with all types of dangerous patients. The most widely used are the barbiturates, the benzodiazepines and antipsychotic drugs. The route of administration and the dosage will vary depending on the situation. Intravenous Sodium Amytal (200 to 400 mg.) or Diazepam (5 to 10 mg.) given slowly over 5 to 8 minutes will allow you to control the acutely dangerous patient. Intra-muscular administration of the same drugs or of haloperidol (5 to 10 mg.) will give slower control of the patient and may require a second dose. There is no currently available intravenous antipsychotic preparation. The high potency, low dose agents such as haloperidol or fluphenazine hydrochloride are generally preferable over low potency, high dose agents like chlorpromazine, for they are less sedating and cause few blood pressure problems. With subacute and chronically dangerous patients, the use of oral antipsychotic agents, especially haloperidol, which appears to help impulse control, is usually effective and safe. Lithium Carbonate has also proven useful for chronically dangerous patients who are explosively violent.

The common core of success in dealing with any dangerous patient is the degree to which the physician acts calmly, deliberately and reasonabiy in the face of what appears to be overwhelming and awesome irrationality. To the extent that you are adequately and appropriately prepared, this will greatly decrease the likelihood of harm occurring to yourself, to the patient or to others, and it will greatly increase the chances that your treatment will be successful.

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Carcinoma of the Lung Invading the Left Atrium

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ABSTRACT—Metastatic carcinoma to the heart is usually by direct invasion of a contiguous tumor, or by pericardial seeding. Tumor can also enter the heart by way of pulmonary veins. The clinical and laboratory features of this entity are similar to those of atrial myxoma. As illustrated by a case recently encountered, recognition of this situation is crucial as surgical therapy may be lifesaving.

It is not commonly recognized that primary lung neoplasms and metastatic disease to lungs can enter the pulmonary veins and left atrium. This situation results in obstruction to blood flow across the mitral valve, systemic embolization of tumor and systemic symptoms suggestive of atrial myxoma. Isolated case reports have been collected and reviewed.[1,2] More recently, two reports have shown that surgical therapy can alleviate the obstruction and prevent further embolization.[3,4] We recently encountered a case whose features are instructive. It is the first case of bronchogenic carcinoma invading the left atrium that underwent surgery.

Awareness of this entity is important to those treating patients with pulmonary neoplasms or metastatic disease, and to cardiologists who may encounter these patients with primarily cardiopulmonary complaints.

Case Report

This 47-year-old white male truck driver had a two month history of dyspnea, fever, malaise and a nonproductive cough prior to his

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admission to an outside hospital in September, 1977. Physical examination at that time revealed decreased breath sounds at the right base. No cardiac murmurs were reported. The chest x-ray showed a question of a right lower lobe infiltrate and right pleural effusion. A lung scan revealed perfusion defects and a diagnosis of pulmonary emboli was made. The patient was anticoagulated.

Two months thereafter, the patient had the sudden onset of right-sided hemiparesis and aphasia. Except for right-sided hemiparesis and Babinski his physical examination was unchanged. A brain scan showed only decreased flow on the left. An echocardiogram was interpreted as mitral stenosis. The diagnosis of mitral stenosis with cerebral emboli was made and anticoagulation was continued.

The patient continued to have symptoms and persistent right lower lobe infiltrate on chest x-ray despite antibiotics. In March, 1978, the patient experienced acute pain and loss of pulse in the left leg. He was transferred to Saint Francis Hospital and Medical Center.

At the time of transfer, the blood pressure was 170/84, the pulse was 100 and the respiratory rate was 20. Roth spots, petechiae and rash were not present. There was no neck vein distention. There were decreased breath sounds at the right base and rales bilaterally. A III/VI pansystolic murmur was present at the apex and radiated to the axilla. No gallop, opening snap or "tumor plop" was present. There was an absence of pulses below the left femoral artery. There was residual right-sided paresis.

The hemoglobin was 10.3 milligram percent and the white blood count was 17,900 per milliliter. Blood cultures were negative. A chest x-ray (Figure 1) revealed, in addition to the right lower lobe infiltrate, a tubular vascular shadow between the infiltrate and the right cardiac border. The electrocardiogram revealed normal sinus rhythm, occasional atrial premature contractions and a question of atrial enlargement.

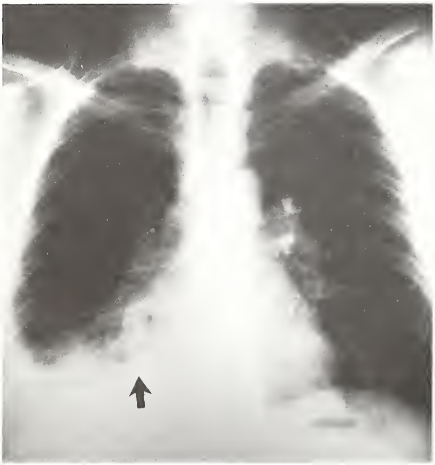

Figure 1

Posteroanterior Chest X-Ray. Note tubular shadow (arrow) felt to be pulmonary vein filled with tumor.

An echocardiogram (Figure 2) was felt to be diagnostic of atrial myxoma. There was a multitude of echoes below the mitral valve in diastole following an initial clear period. In systole, there were some increased echoes below the aorta. The mitral valve had a decreased E-F slope.

Two days following admission, the patient had the sudden onset of right hemiplegia and aphasia. He transiently went into atrial fibrillation. He underwent emergency cardiac catheterization and subsequent open-heart surgery.

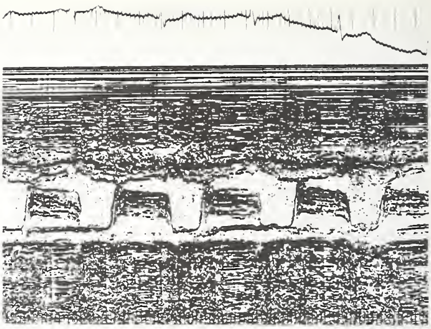

Figure 2

Echocardiogram of mitral valve apparatus showing findings identical to those of atrial myxoma.

A pulmonary artery injection failed to reveal the left atrial mass. However, on left ventriculogram (Figure 3) there was mild mitral regurgitation and a rim of dye outlined a large mass filling the entire left atrium, crossing the mitral valve and entering the left ventricle during diastole. Although simultaneous pressures were not obtained, there was an apparent gradient across the mitral valve. At surgery, the left atrium was approached via a right thoracotomy and right femoral artery cannulation. The left atrium was almost entirely filled with a tumor mass that extended through the mitral valve into the left ventricular cavity. The tumor was extending from the right inferior pulmonary vein, originating from a carcinoma of the right lower lobe. The atrial extension of the tumor was removed by dividing it at the junction of the pulmonary vein and left atrium. The right inferior pulmonary vein was ligated. Attempts to resect the right lower lobe were unsuccessful due to extensive adhesions to the chest wall.

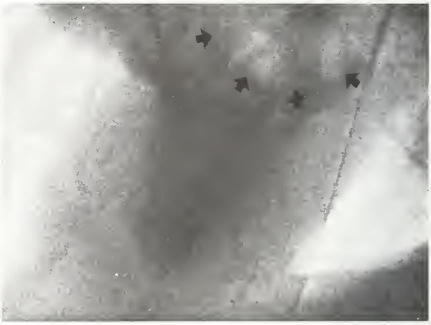

Figure 3

Left anterior oblique left ventricular angiogram showing filling defect in left atrium (arrows).

The tumor was a glistening tan mass with areas of hemorrhage. It was 5.0 centimeters in length and approximately 2.5 centimeters in diameter (Figure 4). The microscopic examination revealed non-cohesive, pleomorphic bizarre cells felt to be most consistent with metastatic undifferentiated bronchogenic carcinoma.

Following surgery, the patient's dyspnea and fatigue abated. A mass was noted in his right forearm which, on excisional biopsy, was found to be histologically identical to the atrial tumor.

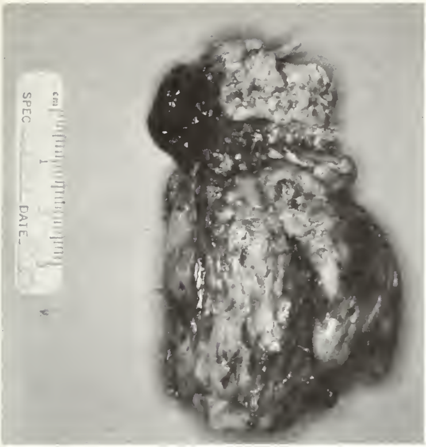

Figure 4
Gross specimen to tumor removed from left atrium growing from the right inferior pulmonary vein.

Discussion

The incidence of metastatic neoplasm to the heart ranges from 0.24 percent to 6.45 percent of autopsies.[5] 5.0 to 18.3 percent of malignant neoplasms involve the heart and great vessels.[6-9] Involvement of the heart occurs in the setting of widespread metastases. It is usually clinically silent. The clinical features, when present, are arrhythmias, conduction defects, congestive heart failure, pericardial effusion or myocardial infarction. Pre-mortem diagnosis is made in only 13.9 to 29.0 percent of cases.[9]

Metastatic disease to the heart is most often a result of direct invasion of heart muscle or pericardial seeding. Although microscopic pulmonary vascular invasion by bronchogenic carcinoma has been demonstrated in 40 percent of cases,[10,11,12] extension through the pulmonary veins into the left atrial cavity, as seen here, is extremely unusual.[1] Onuigbo,[1] Schiller and Madge[2] described and reviewed a total of 19 reported cases of lung tumors entering the left atrium through the pulmonary veins. In addition, Roberts[13] described metastatic choriocarcinoma, and Sterns et al[14] described metastatic rhabdomyosarcoma, extending to the left atrium via pulmonary veins. All of these previous cases were diagnosed post-mortem. Most recently, metastatic chondrosarcoma to left atrium has been reported and has also been successfully treated surgically.[3,4]

Unlike most metastatic disease to the heart, which is clinically silent, patients with this entity are usually dyspneic and often present with cardiorespiratory symptoms. Abrupt cardiorespiratory arrest has been reported.[2] Fever and malaise often suggestive of subacute bacterial endocarditis or myxoma are usually present. Our report and one earlier[3] describe arterial emboli, undoubtedly originating from the friable tumor mass. Bronchogenic carcinoma, as in our case, is the usual underlying tumor, however, several other primary neoplasms with metastases to the lung have been reported to invade the left atrium by the pulmonary veins.[1,2,3,4,12-15] Most patients have widely spread malignancy but, as underscored by our case, neoplastic disease may be limited and not apparent.

As pointed out by Schiller and Madge,[2] patients often have no heart murmurs. If a murmur is present, it is in almost all cases systolic. The diastolic rumble and "tumor plop" of atrial myxoma has not been reported. This may be due to the fact that the left atrial tumors growing from pulmonary veins move little during diastole and flow across the valve is greatly diminished.

We found, in our patient, a vascular shadow running from the lung mass to the right heart border on chest x-ray (Figure 1). Post-operatively, it was not present. We believe this represents the tumor filled right inferior pulmonary vein. Pleural effusion on the right side of the obstructed pulmonary vein is common.

Little has been reported regarding the electrocardiographic findings in this entity. Maclowry and Roberts'[13] case had mildly peaked P waves suggestive of right atrial enlargement. Crus and Stambaugh's[16] patient was in atrial fibrillation. Our patient had transient atrial fibrillation and findings suggestive of left atrial enlargement.

The mass was not seen with the pulmonary artery angiogram, but was clearly delineated by left ventricular angiography with oblique projections. This has also been experienced with left atrial myxoma.[16]

The echocardiographic findings are identical to those of atrial myxoma and must be considered when the pattern is found. The initial misdiagnosis of mitral stenosis was a result of excessive damping of the multitude of echoes behind the mitral valve, a situation that also can occur with atrial myxoma.[18] The present report illustrates the potential of echocardiography in the detection of intracavitary malignancy of the left atrium. In this instance, and in two recent cases, it led to at least temporary lifesaving surgical treatment.

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A Toxic Shock Syndrome

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ABSTRACT—We investigated three cases of a syndrome similar to one described in children. This syndrome affects women who use tampons following the onset of menses and is characterized by sudden onset of high fevers, erythroderma, abdominal pain, voluminous diarrhea, lymphadenopathy and shock. Laboratory tests show elevated BUN, creatinine, evidence of coagulation abnormalities and a leukocytosis with a marked shift to the left. Vaginal cultures consistently grow Staphylococcus aureus.

We propose that Toxic Shock Syndrome is a newly recognized clinical entity that affects young women who use tampons during their menstrual period and develop vaginal Staphylococcus aureus colonization with subsequent evidence of a toxin-like effect. The syndrome is characterized by fever, diarrhea, erythroderma and shock with widespread systemic signs and symptoms.

The last decade has brought the recognition of new infectious diseases such as Legionnaire's Disease as well as syndromes of presumed infectious etiology such as Lyme Arthritis.[1,2] The role of bacterial toxins in the pathogenesis of Toxic Epidermal Necrolysis and antibiotic-induced pseudomembranous colitis has also been appreciated.[3,4] Todd has described in children a severe systemic febrile illness associated with Staphylococcus aureus colonization which has many of the features of a toxin-induced disease.[5]

The paper reports three cases, similar to those described by Todd, all of which occurred in adult women.

Case Reports

Case #1. A 19-year-old white woman presented with the acute onset of nausea, vomiting, fever, rigors and abdominal pain accompanied by voluminous watery diarrhea. She complained of mild arthralgias, sore throat and postural dizziness.

The vital signs were pulse 116, blood pressure 70 mm Hg by palpation, respiratory rate 24 and temperature 104.8°F (40.4°C) orally. The conjunctivae and pharynx were markedly erythematous and the cervical, axillary, inguinal and epitrochlear lymph nodes were tender and enlarged. The heart and lungs were normal. Diffuse abdominal tenderness and rebound tenderness were present with hyperactive bowel sounds. A dark vaginal discharge was also present.

Laboratory data: WBC count 21,000 mm^3, 30% PMN's, 50% bands, 8 metamyelocytes and 3 lymphs. The hematocrit was 38.5 and platelets were normal. The BUN was 40 mg/dl, creatinine 4.8 mg/dl. Urinalysis showed 1+ protein, with 30 WBC's/hpf. The alkaline phosphatase, bilirubin, SGOT and SGPT were normal. The PT, PTT were prolonged and the fibrin degradation products were > 40. A lumbar puncture showed an opening pressure of 190 mm of

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H_2O. The spinal fluid glucose and protein were within normal limits and there was one polymorphonuclear leukocyte. Cultures of blood, urine and spinal fluid were sterile but cultures of the vaginal discharge grew abundant Staphylococcus aureus while stool cultures grew slight to moderate Staphylococcus aureus. Serologic tests for mononucleosis, toxoplasma, cytomegalovirus and ASLO were negative.

The patient was treated with intravenous fluid replacement with 0.9% saline, Solumedrol, Cefazolin and Gentamicin. Two hours after admission the patient developed an intense erythroderma of the face, trunk and proximal extremities which blanced on pressure and spared the circumoral area. The hypotension resolved within 12 hours and the diarrhea resolved in 24 hours but the patient developed edema of the ankles, hands and pre-sacral areas. All signs, symptoms and laboratory abnormalities resolved over the next five days. Ten days after admission the patient underwent desquamation of the hands and feet which began in the peri-ungual areas.

Case #2. An 18-year-old white woman developed sudden onset of fever, chills, nausea and vomiting two days prior to admission. On the day of admission she noted a mild sore throat, myalgias, a nonpruritic erythematous rash of the face and trunk and the sudden onset of generalized abdominal pain with severe, frequent watery diarrhea.

The vital signs were pulse 120, blood pressure 60/30 mm Hg, respirations 16 and temperature 104°F (40.0°C) orally. The throat and conjunctivae were injected and there was palpable tenderness of the cervical, axillary, inguinal and epitrochlear lymph nodes. A diffuse, macular, intense red rash covered the face, trunk and proximal extremities but spared the circumoral area. The lungs were clear; the heart exam was without murmur, gallop or rub. The abdomen was diffusely tender with guarding and rebound tenderness. The bowel sounds were hyperactive. The vaginal exam was remarkable for a reddish discharge.

Laboratory data: WBC count 18,200/mm^3, PMN's 56%, Bands 39%, 3 lymphs, 2 monocytes. The hematocrit was 38.5% and the platelet count was 128,000/mm^3. The fibrin degradation products were >10 but <40. The urinalysis showed 1+ protein and 10-15 WBC/hpf. The BUN was 40 mg/dl and the creatinine 1.7 mg/dl. Bilirubin, SGOT, SGPT and alkaline phosphatase were within normal limits. A lumbar puncture showed an opening pressure of 90 mm H_2O with a normal glucose and protein. There were 2 PMN's.

Cultures of urine, throat, blood and sputum were sterile. Both stool and vaginal cultures grew abundant Staphylococcus aureus. Serologies for toxoplasma, cytomegalovirus, mononucleosis and ASLO were negative.

The patient was treated with intravenous fluids and albumin as well as 12 gms/day of Oxacillin. The diarrhea ceased within 24 hours but she developed marked peripheral edema and shortness of breath. A chest roentgenogram showed bilateral pleural effusions and an enlarging cardiac silhouette. An S_3 gallop was heard. The ECG showed a sinus tachycardia with nonspecific ST and T wave changes. The edema, heart failure and fever resolved over the next 72 hours. Desquamation of the hands and feet developed 11 days after the onset of illness and began in the peri-ungual areas.

Case #3. A 39-year-old white woman developed herpes zoster in the T_{12} dermatome two weeks prior to hospitalization. She was treated with high-dose tapering steroids for 12 days and received no steroids on the day prior to admission. On the day of admission she developed nausea and vomiting followed by copious watery diarrhea and fever with rigors. A mild sore throat, myalgias and nonproductive cough were present. The patient had a history of heart murmur attributed to a bicuspid aortic valve.

The vital signs were pulse 120, blood pressure 60 mm Hg by palpation, respiratory rate 30 and temperature 105.6°F (40.9°C) orally. The conjunctivae and throat were red and a diffuse erythroderma was present over the face, trunk and proximal extremities. There was diffuse tender lymphadenopathy. The lungs were clear and there was an aortic diastolic murmur heard. The bowel sounds were hyperactive with generalized abdominal tenderness guarding and rebound. A vaginal discharge was present.

Laboratory data: WBC count 27,000/mm^3, PMN's 30%, Bands 63%, 4 monocytes, 3 lymphocytes. The hematocrit was 36 and the platelet count was 175,000/mm^3. The urinalysis showed 1+ protein, 3-4 RBC/hpf and 3-5 granular casts/hpf. The BUN was 48 mg/dl and the creatinine was 2.7 mg/dl. Bilirubin, alkaline phosphatase, SGOT and SGPT were all normal. A lumbar puncture showed an opening pressure of 100 mm H_2O with a normal glucose and protein. There was 1 PMN. The PT was 21 sec. (control 9.6 sec.), the PTT was 53.6 sec. (control 22.6 sec.) and the fibrin degradation products were > 10 but < 40.

Cultures of blood, urine and throat were sterile. Cultures of sputum and stool grew slight Staphylococcus aureus. Vaginal culture grew abundant Staphylococcus aureus.

The patient was treated with intravenous fluids and albumin as well as 12 gms/day of Oxacillin with resolution of her fever and diarrhea. On the third hospital day, she developed marked peripheral edema, bilateral pleural effusions and ascites. The cardiac size increased and an S_3 gallop was heard. An ECG showed nonspecific ST and T wave changes with a rate of 48/min. The patient improved over the next five days with resolution of her edema, effusions, ascites and heart failure. Ten days after admission she desquamated the skin of her hands and feet beginning about the peri-ungual area.

Discussion

The three patients described in the preceding case reports all had similar clinical presentations with evidence of a syndrome characterized by dermatologic, musculoskeletal, cardiovascular, renal and gastrointestinal involvement. One case occurred in June 1978, the other two in July 1979. The onset of the disease was sudden with the major characteristics being high fever, erythroderma, abdominal pain, diarrhea, mucous membrane erythema and lymphadenopathy. Laboratory data was consistent with coagulation abnormalities and impaired renal function. There was intense leukocytosis with a marked shift to the left. Cultures of vaginal discharge grew abundant Staphylococcus aureus—an uncommon isolate from this source in our laboratory. Special cultures for Yersinia, Campylobacter and Leptospira were sterile. No serologic evidence of Ebstein-Barr virus, cytomegalovirus, brucella toxoplasma, enteroviruses or streptolysin O was detectable.

The clinical course was characterized by cessation of diarrhea and abdominal pain within 24 hours and resolution of fever by the end of the third day. The role of antibiotics in these cases can not be fully evaluated. Repletion of intravascular volume resulted in the development of peripheral edema probably due to increased vascular permeability and capillary leak. Congestive heart failure with evidence of myocarditis developed in two of the patients. Desquamation of the hands and feet occurred approximately 10 days after the initial symptoms, the desquamation starting in the peri-ungual areas.

The association of colonization with Staphylococcus aureus in these patients and the clinical syndrome itself is similar to that described in children by Todd. Staphylococcus was not cultured from the blood in any of the patients and it is doubtful that true tissue invasion as evidenced by bacteremia occurred. This author postulates that the presence of staphylococcus in the vaginal discharge of these patients was not fortuitous but rather served as a source for the absorption of a staphylococcal toxin which resulted in the clinical illness. Features of this syndrome that are consistent with known toxin effects would include erythroderma with circumoral pallor and subsequent desquamation as seen in scarlet fever when lysogenized strains of group A streptococcus produce erythrogenic toxin. Interestingly, this toxin can also be produced by lysogenized staphylococci and desquamation of the hands and feet is a regular sequela.

Toxin-induced diarrhea is known to occur in the absence of bacterial tissue invasion with enterotoxogenic E. coli, cholera and in antibiotic-induced pseudomembranous colitis. Increased capillary permeability is also a common feature of bacterial toxins.

The Staphylococci isolated from these patients had neither consistent phage types or groups and no distinguishing biochemical markers or antibiotic sensitivities. All of the Staphylococci isolated were resistant to Penicillin G but sensitive to penicillinase resistant semi-synthetic penicillins. Epidemiologic factors are difficult to evaluate in a small number of cases, but the consistency of sex and seasonal occurrence are apparent.

An interesting note is that all three patients were menstruating and had been using tampons during their periods when they developed Toxic Shock. It is well known that tampon products can produce transient mucosal alterations of the vagina[6] but it is too early to tell whether this is an etiologic factor in the pathogenesis of Toxic Shock Syndrome.

These cases are reported to alert physicians to the association of menstruation with tampon use and vaginal Staphylococcus aureus colonization with a syndrome of toxemia, diarrhea, erythroderma and shock.

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Renovascular Hypertension Treated by Percutaneous Transluminal Angioplasty

Interventional Radiology

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Hypertension secondary to renal artery stenosis represents a potentially reversible disorder. The standard surgical technique of renal artery bypass grafting or nephrectomy involve considerable risk, protracted convalescent time and high cost. The case presented illustrates an alternative therapy utilizing the non operative intervention of percutaneous transluminal angioplasty. (PTA)

Case History

A 50-year-old white male was admitted with malignant hypertension characterized by BP 230/130, nausea, cachexia, flank pain left greater than right, BUN 56 and creatine 4.7. Review of his past medical history revealed attacks of pericarditis, thrombophlebitis, peptic ulcer disease treated by vagotomy and pyloroplasty, ethanol abuse, as well as one year of poorly controlled hypertension despite medication with Minipress, Apresoline and Inderol 80mg BID. Radionuclide renal scan and IVP demonstrated a non functioning right kidney and a normal sized, poorly functioning left kidney. Abdominal aortography revealed a severe stenosis of the left main renal artery, complete occlusion of the right renal artery and lower abdominal aorta, (Figure 1) and a nubbin of right kidney filling via capsular collaterals. Renal vein renins lateralized highest on the right, but were also elevated on the left. The patient was considered

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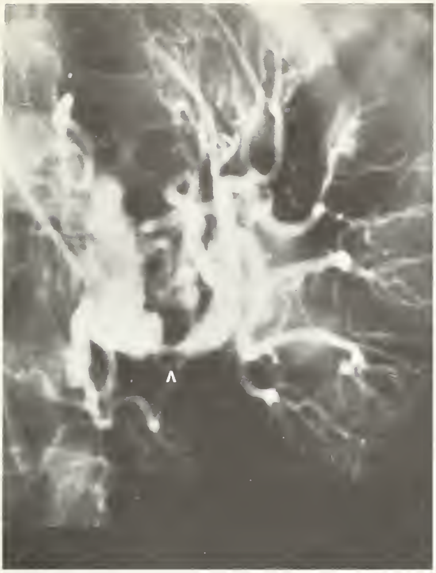

Figure 1
Initial angiogram revealing severe stenosis of the left renal artery.

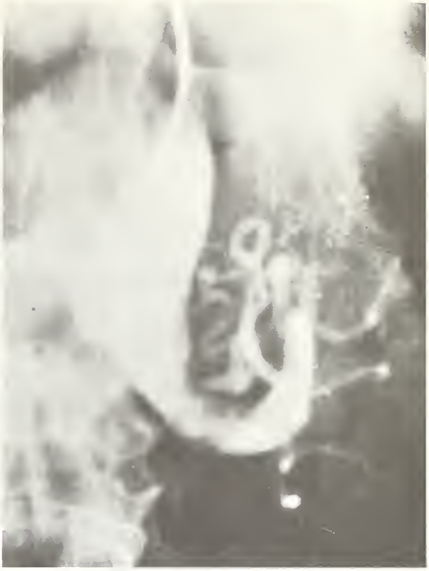

Figure 2
Post dilatation angiogram documenting normal size of left renal artery lumen with occlusion of right artery and lower abdominal aorta.

to be an extremely poor operative candidate and therefore, percutaneous transluminal angioplasty was performed via the transaxillary route using a Gruntzig balloon catheter. Repeat AP and oblique views documented complete dilation of the left renal artery stenosis without evidence of left renal infarction. (Figure 2) The patient was anticoagulated during the procedure and was maintained on heparin for three days thereafter. Two hours following angioplasty his BP was 160/90 and has been maintained at that level with decreased medication and a present BUN 17 and Creatine 1.6.

Discussion

Gruntzig et al initially introduced PTA for the treatment of peripheral arterial lesions, but the coronary, and renal arteries have also been successfully dilated with minimal morbidity.[1] Katzen et al[2] described four patients (two with severe and two with malignant hypertension) who following PTA experienced either rapid reduction in blood pressure and renin levels to normal or became responsive to antihypertension medications.

Despite such encouraging reports, PTA has not been widely utilized.[3] Clearly, a nonoperative approach to the treatment of renovascular hypertension is a welcomed alternative, especially for the patient who is a poor surgical risk and particularly in these times of increasing concern with the cost of medical care.

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Important Advances in Clinical Medicine

Epitomes of Progress — Internal Medicine

Digoxin, Quinidine and Sudden Death

The introduction of quinidine into clinical practice in 1918 marked the beginning of effective therapy for cardiac arrhythmias. The use of quinidine to convert atrial fibrillation to sinus rhythm, however, was associated with a high incidence of sudden death (estimated at between 2 percent and 4 percent). This phenomenon of quinidine syncope occurred almost entirely in patients who were also receiving digitalis. An explanation for this phenomenon has recently been discovered: Addition of quinidine to digoxin therapy causes a dramatic increase in levels of digoxin in the blood.

Levels of the drug in the body are initially determined by body size (volume of distribution) and at steady state by elimination process (clearance). In a typical patient taking digoxin, about 50 percent of the daily dose is excreted in the urine; the remainder is cleared by metabolic and fecal loss. Quinidine decreases the volume of distribution of digoxin by displacing it from tissue binding sites. This leads to a rapid rise in digoxin concentration and an increase in cardiac effect. Quinidine also quickly decreases the elimination of digoxin by both renal and nonrenal routes, leading to a twofold increase in the drug's concentration over a week's time. The combined effects of decreased tissue binding and impaired clearance cause an immediate and sustained elevation of digoxin levels in the body.

Cardiac toxicity may be a consequence of this raised level alone; however, this condition is made more severe by quinidine-induced prolongation of ventricular repolarization (shown by prolonged QT interval), leading to ventricular tachyarrhythmias, syncope and sudden death.

The pharmacokinetic interaction also occurs between digitoxin and quinidine, but not with procainamide or disopyramide. Patients with renal impairment may be particularly at risk because they rely almost entirely on nonrenal elimination of digoxin, which is virtually abolished by the action of quinidine. It would seem prudent to stop digoxin therapy for two days after starting quinidine, and then to resume administration at half the original dose if digoxin levels are to remain the same. The serum concentration should be checked after the patient has been on the new regimen for a week.

Quinidine-digoxin toxicity should be treated by discontinuing administration of both drugs. The rapid elimination of quinidine will lead to a fall in digoxin concentration as the volume of distribution of digoxin increases. Lidocaine, bretylium and overdrive-pacing have proved effective in treating arrhythmias, but drugs which prolong the QT interval, such as procainamide and disopyramide should be avoided.

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Prescribing Exercise

Indications for restricting activity until recently have been more clearly defined than indications for exercise. From data accumulated over the past 20 years, guidelines for prescribing exercise have been developed.

A patient's history, findings on physical examination and a multistage exercise test (MSET) form the basis from which an exercise prescription is determined. From the MSET the target heart rate for exercise (peak heart rate and the maximum work load) is derived and the patient can be advised of other activities of equivalent workload which he or she can safely carry out.

The exercise prescription should specify the frequency, intensity, duration and type of exercise. A minimum of three days of exercise a week, preferably nonconsecutive days, is necessary. High-intensity exercise is neither enjoyable nor safe for cardiac patients. Each patient should be advised to exercise to maintain a heart rate of 70 percent to 85 percent that achieved on the MSET. The exercise most easily undertaken, most readily monitored and most often prescribed is walking. Other endurance activities such as jogging, cycling and swimming can also be prescribed.

The usual exercise session should last about an hour, with 10 minutes of warm-up, 20 to 50 minutes of endurance exercise and 5 to 10 minutes of cool-down. The warm-up and cool-down periods are important and should not be omitted because they serve to develop and maintain flexibility and muscle strength as well as reducing the risk of muscle problems, injuries and fatigue.

A patient's initial level of fitness and clinical status are important considerations when developing the exercise prescription. Typically, an asymptomatic patient who seeks advice concerning exercise is over 40 years old, has a major coronary risk factor or suspected coronary artery disease and has been inactive for some years. Therefore, initial exercise sessions should be short and more frequent. Patients with established cardiac disease or a chronic illness will also need a slow initiation into exercise and special attention to medications that may affect such exertion. Early low-level treadmill testing and exercise for patients after myocardial infarction and myocardial revascularization operations are safe and advantageous. Periodic review and repeat MSE testing are required to adjust the target heart rate with exercise.

Exercise is a lifelong commitment and is most valuable when it is a component of a treatment program that deals with all the cardiovascular risk factors that can be modified or controlled.

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Intracavitary Electrodes for Diagnosis and Treatment of Arrhythmias

Although several articles have reported the use of right atrial intracavitary electrode electrogram monitoring and therapeutic pacing for diagnosis and treatment of atrial arrhythmias, this modality unfortunately has had limited use.

It is well recognized that an arrhythmia such as atrial flutter with 2:1 atrial ventricular conduction may be extremely difficult to diagnose. This form of atrial flutter may be confused with sinus, atrial or junctional tachycardia. If aberrant ventricular conduction is present, confusion with ventricular tachycardia is likely. An intracavitary right atrial electrocardiogram can be helpful in differentiating these arrhythmias.

The use of an intra-atrial electrogram provides magnification of the atrial electrical activity. If an atrial electrocardiogram (ECG) is compared with simultaneous surface leads using any standard three-channel ECG machine, diagnosis of the arrhythmia is greatly facilitated.

Once the diagnosis is established, the same intracavitary electrode can be used for rapid atrial pacing with an external pacemaker unit designed to pace up to rates of 800 beats per minute. Virtually all forms of tachyarrhythmia with the exception of sinus tachycardia, type II atrial flutter, atrial fibrillation and ventricular fibrillation may respond to rapid atrial pacing with conversion either to sinus rhythm or to a less threatening arrhythmia that is amenable to combined medical treatment. If type I atrial flutter with rapid ventricular response rate recurs despite interruption with right atrial rapid pacing, a more desirable atrial tachyarrhythmia may be induced by pacing the atria at a rate of 450 to 500 beats per minute to produce atrial fibrillation. The ventricular response rate may then be controlled by adding digitalis to the treatment regimen.

In a recent review the use of cardiac electrodes in the diagnosis and treatment of tachyarrhythmias was summarized. The use of rapid atrial pacing has few adverse side effects and is desirable in acutely ill patients who present a high anesthetic risk for external electrical cardioversion.

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Vasodilator Therapy for Chronic Congestive Heart Failure

Standard medical therapy for chronic congestive heart failure includes reduction of cardiac workload, restriction of salt, and administration of diuretics and digitalis. In patients who do not respond well to this regimen, admission to hospital may be required to control symptoms and signs of heart failure. Over the past several years, vasodilator drugs, which are given in addition to digitalis and diuretic therapy, have become available. Results suggest that many patients will benefit from the addition of these drugs and will be symptomatically improved.

Vasodilator drugs can be divided into several subgroups, depending on their mechanism of action. Arteriolar dilators, such as hydralazine, reduce systemic vascular resistance, making it easier for the heart to pump blood throughout the body. This increase in cardiac output is usually accompanied by little or no change in heart rate, mean arterial pressure, or left and right atrial pressures. Vasodilators that predominantly dilate peripheral veins, such as the nitrates, work by a different mechanism. Because 75 percent of the blood volume is located in the peripheral venous system, dilation of veins will tend to increase the relative amount of blood in the peripheral veins and reduce the volume of blood in the chest. This is helpful in lowering left and right atrial pressures, thereby relieving the signs of pulmonary or systemic congestion.

The nitrates can be administered effectively by the sublingual, oral or topical route. Because of their shorter course of action when given sublingually, these drugs are usually administered orally or topically to patients with chronic congestive heart failure.

A combination of arteriolar and venodilating drugs, which can reduce right and left atrial pressures and increase forward cardiac output, have been extremely beneficial in many patients with severe chronic congestive heart failure. A single drug that has combined arteriolar and venodilating effects is prazosin hydrochloride. Some studies have shown hemodynamic tachyphylaxis with prazosin therapy, wherein the magnitude of the hemodynamic response diminishes with successive doses. Nevertheless double-blind placebo-controlled exercise studies have shown improved exercise tolerance in patients receiving this post-synaptic alpha-adrenergic blocking agent. Several other new drugs are being tested to evaluate their potential as therapeutic agents in chronic congestive heart failure, and it is likely that a variety of drugs may be available in the future.

In patients admitted to hospital for chronic refractory heart failure, it is helfpful to pass a balloon-tip Swan-Ganz catheter for measurement of hemodynamics. The immediate response to vasodilators can then be titrated to achieve an optimal dosage schedule before a patient is discharged from hospital. In patients with mitral regurgitation, both arteriolar and venodilators have been particularly beneficial. The administration of these drugs decreases the regurgitant fraction and left atrial pressure while increasing forward cardiac output. Because many patients with chronic congestive heart failure have some degree of mitral regurgitation, vasodilators are a particularly attractive form of adjunctive therapy in this sub-group.

In summary, vasodilator drugs provide an important form of adjunct therapy in patients with severe, chronic congestive heart failure. Available drugs are effective, and new drugs are being evaluated. Results to date suggest that this form of therapy has a permanent place in the pharmacological management of heart failure.

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Resurgence of Plague

In recent years there has been an increasing incidence of plague reported from endemic areas of the western United States. This is due in part to natural fluctuations of the plague reservoir involving the organism *(Yersinia pestis),* its vector (fleas) and hosts—small mammals indigenous to the region. However, a more important reason for this increase is greater contact between humans and animals carrying the disease. Many cases occur on Indian reservations where the lifestyles of the Native Americans bring them into closer contact with the sources of infection. However, increased popularity of rural life-styles as well as backpacking and camping activities has increased the incidence of plague in other than Native Americans. Therefore, physicians practicing in urban and nonendemic areas also need to be aware of the possibility of the disease occurring in patients who have visited endemic areas.

The disease has an incubation period of two to six days, followed by initial manifestations such as malaise, fever, and pain and swelling in the area of regional lymph nodes (usually inguinal or axillary). Progression of the disease is variable; however, in most untreated patients septicemia develops. Pneumonic forms are unusual but do occur.

Diagnostic efforts should be expeditious, including aspiration of lymph nodes (buboes), cultures of blood and sputum, and examination of cerebrospinal fluid. Aspirated material should be stained with Wayson or Giemsa stains to delineate the bipolarity of the organism. A fluorescent antibody method is available for rapid presumptive diagnosis. Serologic testing can be done for later confirmation.

Streptomycin is the antimicrobial drug of choice. Tetracycline and chloramphenicol are good alternative drugs. Studies are underway to determine the efficacy of other aminoglycosides. Usual supportive measures should be used for controlling endotoxic shock that may complicate septicemia due to plague. The patient should be isolated and his or her contacts found and treated with antimicrobial prophylaxis where appropriate.

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Pneumococcal Polysaccharide Vaccine

With the advent of effective antibiotic therapy in the late 1940's, there has been less concern with pneumococcal infections. However, the problem has not disappeared and, in spite of the effectiveness of treatment, more than 400,000 cases of pneumococcal pneumonia occur annually in the United States, with a mortality of between 5 percent and 10 percent. This means that as many as 40,000 people a year die from pneumococcal pneumonia. It is also estimated that there are between 3,000 and 5,000 cases of pneumococcal meningitis each year, and that approximately 6 percent of these cases are fatal. At least 83 types of pneumococci are responsible for the infections, and these strains can be identified by their capsular polysaccharides. Patients at high risk for pneumonococcal infections are those with sicklecell anemia, those in whom the spleen is absent or malfunctioning, and those with agammaglobulinemia, multiple myeloma, nephrotic syndrome, cirrhosis or alcoholism.

Attempts to develop pneumococcal vaccines began more than 50 years ago. A trivalent vaccine tested during World War II was found to be effective. Another vaccine which contained several polysaccharide types was licensed and produced in the United States in the mid-1940's. However, when antibiotics became available, its production was discontinued.

Recently, a polyvalent vaccine that contains 14 of the most prevalent capsular types has become available in the United States. These 14 types account for 80 percent or more of the incidence of pneumococcal disease occurring in this country. The vaccine has been widely tested in susceptible groups and has been found to be more than 80 percent effective.

The Public Health Service Advisory Committee on Immunization Practices of the Center for Disease Control has issued the following guidelines for the use of the pneumococcal vaccine:

- Mass immunization is not recommended at present.
- Use in treating pregnant women or children under two years of age is not advised.
- The vaccine is of greatest value to the following: Anyone over two years of age lacking a spleen, anatomically or functionally, such as those with sickle-cell disease, and persons over two years of age in whom risk of pneumococcal disease is higher because of chronic illnesses such as diabetes mellitus, functional impairment of cardio-respiratory, hepatic or renal systems or lack of immune responsiveness. Because the risk of development of or death from pneumococcal disease increases with age, the benefits of receiving the vaccine also increase with advancing age.

A single dose of 0.5 ml of vaccine is given subcutaneously or intramuscularly. The vaccine should not be injected intravenously. Also, booster injections should not be given more than once every three years. The only adverse reactions are local erythema and soreness at the injection site, which usually last less than two days. A low-grade fever with temperatures of less than 38.3°C (101°F) may occur during the first 24 hours.

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New Conceptual and Technical Advances in the Care of Diabetes

Recent conceptual and technical advances in the management of diabetes mellitus should have a major impact on delivery of health care. These advances include (1) more stringent but rational diagnostic criteria, (2) improved assessment of metabolic control and (3) new technology in the administration of insulin.

Over the past two decades, several large studies have shown that diabetes-associated complications occur in specific subgroups of glucose-intolerant persons. New criteria more accurately restrict the diagnosis of diabetes to those who are at increased risk for the development of specific complications such as ketosis, retinopathy and nephropathy. Normal levels of glucose in venous plasma should be less than 115 mg per dl, and two hours after oral administration of glucose they should be less that 140 mg per dl. To be considered diabetic a person must have (1) classic symptoms of diabetes such as polyuria, ketonuria and unequivocally elevated levels of circulating glucose, (2) fasting venous plasma levels of glucose that exceed 140 mg per dl on more than one occasion or (3) one or two hours after glucose ingestion, venous plasma levels of glucose that exceed 200 mg per dl on more than one occasion.

These criteria define a subgroup of persons who have (1) a glucose intolerance in the normal to diabetic range, (2) a risk of 1 percent to 5 percent per year for the development of diabetes and its complications and (3) a high potential for normal glucose tolerance in the future. New criteria have also been suggested for children and pregnant women. After the diagnosis of diabetes is established, it is suggested that further subgroups be identified, primarily to determine whether a patient requires insulin (insulin-dependent diabetes) or some other treatment regimen (noninsulin-dependent diabetes). Although these concepts are not new, this terminology focuses attention toward a treatment regimen independent of age or habitus. Because of the ambiguities of the terms juvenile onset and maturity onset, it is suggested that they no longer be used. Much of the confusion involving the pathogenesis, complications and treatment of diabetes results from inadequate information concerning the diagnosis, as well as mixing of patients with dissimilar types of diabetes.

Routine clinical assessment of the metabolic abnormalities associated with diabetes is less than ideal. Insulin is a major regulator for physiological processing and storage of nutrients. During states of insulin bioinactivity, regardless of whether the cause is islet secretory impairment or peripheral insulin resistance, major alterations occur in lipid, protein and carbohydrate homeostasis. For the past several decades, metabolic control has been evaluated by sharp changes in glucose levels in urine or blood. Routine estimates of lipid and protein levels are virtually nonexistent. Recent technical advances in the specific estimation of erythrocyte hemoglobin A1C, a naturally-occurring glycosylated hemoglobin species, have provided for a longer-range assessment (one to three months) of metabolic control. Specific hemoglobin A1C assays correlate with circulating glucose concentrations, are available for routine clinical use and, when inappropriately elevated, provide a marker indicating the necessity for more stringent metabolic control. Although hemoglobin A1C levels offer an improvement for assessing metabolic control with regard to both health care delivery and research, the assay apparently remains restricted to glucose homeostasis.

Recent technology applied to improving metabolic control of insulin-dependent diabetes has proved effective in research, and has limited but immediate health care uses. One of these bioengineering products incorporates a blood glucose sensor and computer analysis to direct the intravenous infusion of insulin. This glucose-controlled, artificial pancreas reliably restores circulating glucose levels to normal, and other metabolic measurements to near normal, irrespective of meal patterns. This device is also useful for complex surgical, medical or obstetric care of patients with diabetes. These units will become more generally available over the next few years; at present, the San Francisco and Irvine campuses of the University of California are using them for health care delivery and research. For outpatient care of persons with insulin-dependent diabetes, portable, nonglucose-controlled, variable rate, subcutaneous infusion pumps are available. These instruments are also in active use for research and patient care. The portable insulin pump has been shown to improve circulating glucose, lipid and amino acid levels. Associated with improved metabolic control resulting from use of these two devices, is improvement in control of urinary albumin leakage and improved nerve conduction velocities after only three weeks and 48 hours, respectively. Several caveats remain unexplored such as the psychosocial impact of such devices on patients, but these and other issues are being investigated.

New conceptual and technical advances in the understanding and management of diabetes has had a major impact on health care delivery and research. It is hoped that such changes will improve the course of patients with chronic diabetic complications.

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Endoscopic Sphincterotomy in the Therapy of Extrahepatic Cholestasis

Since 1970, endoscopic retrograde colangiopancreatography (ERCP) has become an established diagnostic technique in the management of pancreatic and biliary tract disease. The ability to direct instruments through the duodenoscope into the biliary ducts subsequently influenced the development of endoscopic sphincterotomy (ES), a sophisticated electrosurgical technique for the removal of common duct stones (CDS). Widely used first in Japan and Europe, and later in the United States, endoscopic sphincterotomy is now an established, clinically accepted therapy for removal of retained or recurrent CDS after cholecystectomy. Other situations in which it may be of value are CDS in some high-risk patients or those with pepticemia and intact gallbladders (ES may be either a substitute or preparation for a later operation); short distal common bile duct strictures, and functional obstruction of the distal bile duct, often called papillary stenosis (PS). Papillary stenosis remains an ambiguous clinical entity and requires further study to confirm the role of ES in its management. Endoscopic sphincterotomy should be avoided when patients have a severe coagulopathy, a long stricture of the common duct or stones larger than 2.5 cm.

The technique most commonly used has been presented in detail in the literature but it continues to be studied and improved. A catheter designed for electrosurgical use is passed through the duodenoscope into the distal biliary tree where a short incision is created. CDS may be extracted with a balloon-tipped catheter, Dormia basket or allowed to pass spontaneously. The incision often remains as a permanent choledochoduodenostomy.

The results of endoscopic sphincterotomy as carried out by experienced European and American endoscopists have been similarly successful. ES permits extraction of stones or their spontaneous passage in 88 percent to 92 percent of patients receiving this therapy. Relief of symptoms following ES in carefully selected patients with PS has yielded promising results. This author's (F.C.S.) series includes 38 successful CDS extractions in the 41 patients undergoing the procedure and 2 patients who have been successfully relieved of symptoms secondary to papillary stenosis.

Reported complications include bleeding, retroperitoneal perforation, pancreatitis and cholangitis occurring cumulatively in 8 percent to 10 percent of cases. Subsequent operations have been required in 2 percent to 3 percent of these, with an overall mortality of 1 percent to 1.5 percent. The present series includes two patients who had minor bleeding and one patient in whom both pancreatitis and perforation required an operation, for an overall complication rate of 8 percent. No deaths occurred among the 43 patients in whom ES was carried out.

The long-term outcome of ES appears to be comparable to that obtained by laparotomy. By contrast, morbidity, mortality and cost, especially when considering the number of hospital days involved and cost of ancillary procedures, are substantially lower than those required for laparotomy. As with ERCP, the skill required to master ES demands extensive experience and competent training. Potential complications of the procedure require immediate availability of and a good working relationship with an experienced biliary tract surgeon. Therefore, the procedure should be made available only in those centers where there are physicians with established expertise who can be assured of cooperative support.

Although it carries known mortality and morbidity risks and demands sophisticated expertise, ES is an established, cost-effective clinical technique now available in many regional centers throughout the United States.

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Granulocyte Transfusion: Its Current Status

Erythrocyte, platelet and plasma components of whole blood have been available for prophylactic and therapeutic treatment for many years. However, the recent availability of sophisticated and economic equipment for safe extracorporeal blood cell separation has enabled many blood banks to offer clinicians fresh whole blood preparations enriched with leukocytes (so-called leukocyte or granulocyte transfusions). Two procurement methods are used at present: filtration leukapheresis (FL), and continuous flow or intermittent flow centrifugation leukapheresis (CFC, IFC). Of these two methods, the CFC and IFC products are associated with fewer side effects for donors and recipients, and contain better functioning granulocytes. Because of these reasons the FL procedure has been abandoned by the National Red Cross and probably will not be widely used in the future by others.

Leukocyte transfusions are of greatest value in the treatment of patients with neutropenia secondary to diminished neutrophil production. They can be used prophylactically to prevent bacterial infections or therapeutically to treat established bacterial infections. Prospective, randomized clinical trials of both prophylactic and therapeutic transfusions have been recently completed. It has been found that HLA matched prophylactic granulocyte transfusions decrease the incidence of bacterial infection developing in patients with neutropenia who are receiving bone marrow transplants; however, it has not been found to be any better than laminar air flow isolation. In non-HLA matched transfusions, however, the incidence of alloimmunization against leukocyte antigens severely limits its prophylactic use. In several therapeutic trials involving neutropenic patients with acute leukemia and aplastic anemia, transfused patients appeared to fare better than nontransfused patients; although, in some studies the differences were not statistically significant. This is due to variability in the types and amounts of granulocytes transfused in the different studies. Transfusions were of no benefit in patients with "fevers of undetermined origin" or in patients with neutrophil counts of over 1,000 perμl. The efficacy of granulocyte transfusion was directly related to the ability of the product to raise the granulocyte count in the recipient, so that smaller patients, or those given large daily or twice daily transfusions were more likely to benefit. In considering this form of therapy, two points should be noted. First, although some patients' conditions clearly improve with therapy, no studies have shown a definite increase in survival rates for patients receiving granulocyte transfusion. Second, no benefit is achieved in recipients for whom results of bone marrow examinations would predict recovery of neutropenia within three to five days. Granulocyte transfusions probably are most effective in causing improvement or cure of clinical infection when used in the following circumstances: (1) The patient has documented serious bacterial infection that remains unresponsive after 24 to 48 hours of parenteral broad spectrum antibiotic treatment, (2) the patient's neutrophil count is less than 500 per μl, with absent neutrophil precursors in the marrow, (3) healthy compatible donors, equipment and personnel for long-term support are available and (4) the patient has a good prognosis if recovery from the infection is obtained.

In spite of good evidence that granulocyte transfusions can alter the clinical course of serious bacterial infections in some patients with neutropenia, the modest overall benefit and inconvenience of daily procurement dictate that this therapy in general clinical practice should be reserved for selected patients.

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Progress Toward Effective Antiviral Agents

While many viral infections are associated with illness and loss of work, serious consequences from such infections are unusual. However, aggressive treatment of diseases such as neoplasia or renal failure often involves therapies that alter the immune system and predispose patients to more serious viral infections. Thus, progressive viral diseases in immunosuppressed patients and occasional severe infections in otherwise healthy persons have served as incentives to the development of effective antiviral compounds. Recent events have suggested that such therapy exists. Three distinct substances have proved effective against viral infections when used in other than topical applications.

Amantadine is known to be an effective prophylactic agent when used to prevent infections with influenza A. This drug appears particularly useful in patients with serious underlying diseases who are exposed to outbreaks of influenza caused by this strain before immunization can be expected to produce reasonable antibody titer. Amantadine also appears of therapeutic value after the first symptoms of influenza have developed. However, its usefulness in this regard may be limited, and no information is available to suggest whether it is effective against influenzal pneumonia, the most hazardous complication.

Adenine arabinoside, a relatively new agent, has proved of definite benefit in patients with encephalitis due to herpes simplex virus, and has been effective in reducing mortality. In addition, adenine arabinoside may be effective in herpes zoster and disseminated herpes infections in newborn infants.

Interferon, a natural body protein, has been produced in vitro in quantities sufficient for administration to patients and has been found effective against herpes zoster. However, it remains both difficult and expensive to produce.

In addition to the parenteral drugs mentioned, idoxuridine has long been an effective topical therapy for treatment of certain forms of herpetic keratitis, and topical adenine arabinoside appears even more beneficial in ocular disease.

Newer agents with considerable promise are being tested. They include acycloguanosine (Acyclovir), which is much more effective in vitro than adenine arabinoside against herpes viruses, and the glucose derivative 2-deoxy-D-glucose, which has been reported to be beneficial for genital herpes infections when applied topically.

Thomas C. Cesario, MD

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Immunodiagnosis of Viral Hepatitis

Laboratory diagnosis of hepatitis types A, B and non-A/non-B (abbreviated HA, HB and NANB, respectively) can be established by testing immunologic responses to the viral agents of HA and HB; NANB is established only by exclusion (Table 1).

Table 1

PRACTICAL GUIDE FOR THE INTERPRETATION OF SEROLOGIC MARKERS OF VIRAL HEPATITIS

Clinical Interpretation	*IgM Anti-HA**	*HBsAg*	*HBeAg*	*Anti-HBe*	*Anti-HBc*	*Anti-HBs*
Acute HA	+	−	−	−	−	−
Incubation period or early acute HB	−	+	+	−	−	−
Acute HB	−	+	+	−	+	−
Fulminant HB	−	+	−	−	+	+/−
Convalescence from acute HB	−	−	−	+	+	+/−
Chronic HB	−	+	+/−	+/−	+	+/−
Persistent HB carrier state	−	+	−	+	+	−
Past infection with HB virus	−	−	−	−	+	+
Infection with HB virus without detectable (excess) HBsAg	−	−	−	−	+	−
Immunization without infection	−	−	−	−	−	+
Non-A/non-B hepatitis by exclusion of markers for HA and HB	−	−	−	−	−	−

Anti-HA = hepatitis A antibody; HBsAg = hepatitis B surface antigen; HBeAg = hepatitis B "e" antigen; anti-HBe = hepatitis B "e" antibody; anti-HBc = hepatitis B core antibody; anti-HBs = hepatitis B surface antibody.

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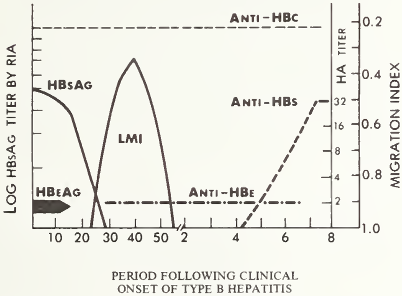
*Clinically unrecognized infection occurring in childhood accounts for the high incidence of IgG anti-HA antibodies in 80 percent to 90 percent of adults in underdeveloped countries as compared with 25 percent to 50 percent of adults in Europe and the United States.

In HA, the presence of anti-HA in the IgM class of immunoglobulins suggests a current or recent infection, whereas anti-HA appearing in the IgG class indicates infection occurring in the past and confers immunity to HA.

The temporal changes in various markers during the acute phase of HB are shown in Figure 1. Although the clinical minifestations of acute HA, HB or NANB are similar, a chronic carrier state and chronic liver disease of more than six months duration are recognized only for infection with HB or NANB agents. Nearly 10 percent of patients with acute HB have unresolved hepatitis, frequently persisting for years, and often progressing to a form of chronic hepatitis. The pathogenic mechanisms responsible for the persistence of viral infection and the chronic hepatic condition are unclear.



Anti-HBc = hepatitis B core antibody; Anti-HBe = hepatitis B "e" antibody; Anti-HBs = hepatitis B surface antibody; HBeAg = hepatitis B "e" antigen; HBsAg = hepatitis B surface antigen; RIA = radioimmunoassay.

Figure 1

Immunologic response to HBsAg, HBcAg and HBeAg during acute and convalescent phases of type B hepatitis. The fact that leukocyte migration inhibition (LMI) with purified HBsAg is present but disappears after about four weeks suggests that hepatitis B virus infection may be self-limited. In contrast, the LMI test is negative in persistent or chronic cases of hepatitis B.

Asymptomatic carriers of HB, estimated to number about 900,000 in the United States, and possibly 150 million worldwide, are believed to serve as an epidemiologic reservoir for HB virus infection. Because a large percentage of patients with primary hepatocellular carcinoma are positive for the hepatitis B surface antigen (HBsAg), HB virus is suspected to be oncogenic. Because the hepatitis B surface antibody (anti-HBs) is protective against reinfection with HB virus, HBsAg purified from the plasma of chronic carriers is being evaluated as a prophylactic vaccine against HB and its sequelae.

Girish N. Vyas, PhD
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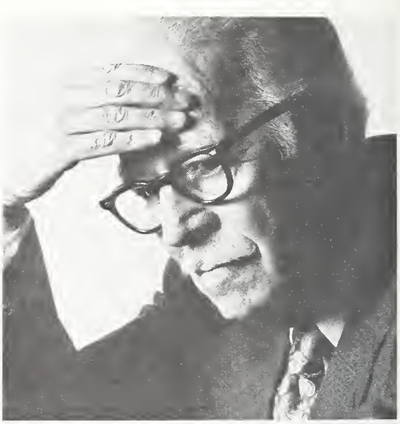

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The Physician Assistant as Resident on a Surgical Service

J. JEFFREY HEINRICH, PA-C, BRUCE C. FICHANDLER, PA-C,
MALCOLM BEINFIELD, M.D., WILLIAM H. FRAZIER, M.D.,
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A variety of innovative programs has been developed to educate a new health professional commonly referred to as a physician assistant (PA). The first such program was begun at Duke University, Durham, NC, in 1965. These graduate-level programs are designed to teach the PA how to deal with the common problems seen daily in a general medical practice. The PA works as a dependent practitioner under the direction and supervision of a physician. The depth of his/her clinical experience allows a PA to help in making decisions regarding common patient problems, including diagnosis and treatment.

There are presently more than 8,000 formally trained PAs in practice. They are being used by many physicians in a wide variety of clinical settings to increase and expand the health care services available to the public.

Recently, there were two developments that suggested there may be an increased need for this type of health professional in surgery. The Study on Surgical Services for the United States, carried out by the American College of Surgeons and the American Surgical Association, indicated that there will be a reduction in the number of physicians entering surgical residency training programs during the next ten years. The Health Professions Educational Assistance Act of 1976 (Public Law 94-484 and Amendment PL-95-83) is expected to reduce the total number of foreign medical graduates immigrating to the United States. Careful review of the educational aspects of physicians' residency programs and other factors have resulted in a decrease in the number of free-standing surgical residency programs, primarily in community hospitals. This has resulted in a manpower shortage for continuous in-house surgical expertise, both for preoperative and postoperative care, and for operative assistants in some of those institutions.

To meet this problem, a one-year postgraduate educational program was developed to educate PAs to function as PA house officers on the surgical service. It was our hope that after this one-year residency the then designated surgical PA could be employed by surgeons or by a hospital that did not have a surgical residency or where the size of the surgical house staff of physicians could be reduced with such help.

In September 1976, Norwalk Hospital and the Yale University School of Medicine jointly accepted their first class of ten PA residents in surgery. The program was primarily designed to enhance the overall skills of the trained PA with a broad emphasis on the preopera-

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tive, intraoperative and postoperative management of the surgical patient.

A structured curriculum was designed to assist in development of cognitive and technical skills and to provide a basis for sound surgical judgment. To accomplish this goal, the program was divided into two phases, a four-month didactic phase that takes place at Yale University School of Medicine and an eight-month clinical phase at Norwalk Hospital.

A major emphasis at Yale is to familiarize the resident with the pathophysiology of surgical diseases. During this phase, both structured and unstructured didactic and practical instructions are provided. The structured curriculum consists of three main courses: animal surgery, anatomy, and a lecture series on the surgical specialties. The unstructured curriculum constitutes all of the various medical and surgical conferences held in the medical center, the Yale PA program lectures, and a series of lectures on surgery for medical students. The animal surgery course helps to develop technical proficiency in manual skills, thus making the residents better surgical assistants.

A course in anatomy using cadavers is given to provide the necessary review of this important subject. The emphasis in it is on the development of an understanding of the clinical importance of anatomy, an approach reinforced by having clinical surgeons as instructors. Clinical rotations comprise part of the resident's responsibilities while at Yale University. Of the five rotations, four are mandatory and one is elective. The mandatory rotations are plastic surgery, emergency service/trauma, surgical intensive care, and anesthesiology. Any other specialty rotation is available to the residents for their elective.

The eight months of the program at Norwalk Hospital are devoted to a didactic and broadly based clinical rotation program. The didactic curriculum is comprised of daily lectures that encompass the following four major areas: (1) preoperative and postoperative care including cardiopulmonary resuscitation, fluid and electrolytes, and hematologic abnormalities; (2) surgical techniques; (3) general surgery; and (4) disease processes including pathophysiology, diagnosis, and evaluation of specific organ systems.

The majority of the PA resident's clinical time is spent on the General Surgery Service at Norwalk Hospital. Among his/her duties is the gathering of a data base on patients admitted to the surgical service that includes a history, physical examination, and laboratory data. This is written into the patient's record and reviewed by a surgeon. Admission and preoperative orders are written under the direction of the responsible attending surgeon; in the operating room the resident serves as a first or second assistant. Unlike a surgical residency program for physicians, the intent of the intraoperative training is to develop skills of a surgical assistant rather than those of an independent operating surgeon. This represents a fundamental and critical difference in orientation and goals compared with a standard physician-based surgical residency.

The questions posed at the beginning of the program have been answered—some completely, some in part, and for several, other questions were raised. The first question as to whether such a program would provide for good care of surgical patients and involve the surgical staff in worthwhile teaching objectives has been affirmatively answered. Good care with in-house capability has been provided. The surgical PA completing this program can perform certain aspects of inpatient care with a level of experience beyond a beginning surgical resident.

Secondly, the program has been accepted enthusiastically by patients on the surgical services. These enthusiastic PAs, graduates of American colleges, can communicate clearly, easily, and pleasantly with patients. They have the time to listen, to commiserate, and to translate. The reception by surgeons has been equally enthusiastic. Physicians and residents in other specialties have had concerns about and problems relating to the program. The basic question here is, "Can there be residencies for physicians in the primary care specialties, i.e., internal medicine and pediatrics, in an institution but using a different approach in surgery?" This question has not been answered completely as yet. While the surgical PA may provide an initial evaluation on a consultation, the final decision on management obviously must rest with one of the attending surgeons. Acceptance of the PA by the resident physician in medicine, used to dealing with surgical residents, comes only with time and familiarity with the program and the people involved in it.

The program has proven to be worthwhile for PAs that enroll. It has been most enthusiastically received by PAs; competition for admission has been great; excellent people from around the country now apply. The graduates have all been highly sought after, have received a number of job offers, and have been able to choose the exact area in which they would like to work. Their positions and role, however, do not allow much upward job mobility. Despite working on a service for a given number of years, there is a finite point to which responsibility can be delegated. Thus they can seldom if ever expect to function much beyond the level of a second or at best third year resident physician. This could be a problem in the future in terms of permanent job satisfaction.

Whether there are real or imagined hazards in the involvement of PAs in this type of patient-care must also be answered. In this regard, it can be said that the PAs in this residency program are not trained to be surgeons in helping to workup patients and care for

Whether there are real or imagined hazards in the involvement of PAs in this type of patient-care must also be answered. In this regard, it can be said that the

PAs in this residency program are not trained to be surgeons, they do not perform operations on patients (other than minor procedures—cutdowns, etc.), but they do assist. They are also trained to work with surgeons in helping to workup patients and care for them; they work strictly under the supervision of a trained surgeon. They do not complete the full residency required for MDs. Thus, the surgical PAs are supervised and they assist; they are surgeon-extenders. When they are employed by an institution to function in this way, the chief of surgery of the institution must be in charge of their activity.

The question as to whether a PA with this training can be the first assistant in the operating room must also be considered. It has been an established tradition in surgery that the assistant in the operating room must be a trained individual and be capable of completing the operation if something happens to the surgeon. However in many surgical training programs the assistant is commonly a junior resident. Therefore, it does seem appropriate that the trained surgical PA can provide assistance in the operating room as the first assistant or as the only assistant in rather straightforward, simple procedures.

The final question is, "Can the Yale/Norwalk experience serve as a model for other excellent community hospitals where an independent surgical residency has not been feasible or could or should be discontinued?" We believe it can serve as a model both to develop similar programs at other institutions and to show how PAs can function on a surgical service. The individuals completing this program have been sought for other institutions. They have done an excellent job in the institutions where they have gone to work, and they do, indeed, provide help in the care of surgical patients in hospitals. Some community hospitals affiliated with a medical school may wish to consider such a residency program for PAs who have completed their basic educational program. Others may wish only to employ graduates to provide capable in-house care of surgical patients and, thus, take the place of residents who may no longer be available.

This program is an experiment in creative problem-solving to fill surgical manpower needs. It provides an educational mission within the hospital and also provides well-trained individuals to serve as surgeon extenders in patient care. It is recommended for those hospitals with a commitment to education where a full surgical residency for physicians is not possible or feasible.

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Dysphagia

Introduction

DR. JOHN A. KIRCHNER: This morning we would like to discuss a symptom that frequently presents itself to the otolaryngologist: difficulty in swallowing; and to confine this to the hypopharynx, an anatomical area that includes the pyriform sinuses, base of tongue, cricopharyngeus muscle and postcricoid area. The proper function of these various structures is what produces the normal swallow, whereas the improper function or absence of any of these structures can produce dysphagia, aspiration, cough and choking.

In this patient, for example, the base of the tongue has been largely removed for a carcinoma. He subsequently complained that every time he tried to swallow liquids, he coughed and choked. Barium study showed that the material simply formed a large puddle in the pharynx where the base of tongue was deficient, allowing some of the bolus to spill over into his trachea.

A structure that is often involved in dysphagia is the cricopharyngeus muscle. Although the inferior constrictor and the cricopharyngeus are both striated muscles, they react differently physiologically. If, for example, the superior laryngeal nerve is electrically stimulated, a reflex response in the recurrent laryngeal nerve results and two different responses occur in the cricopharyngeus and in the inferior constrictor. The cricopharyngeus shows an evoked response and also a reflex response whereas the inferior constrictor gives only the evoked response. Another illustration of this shows that if the superior sympathetic cervical ganglion is stimulated, there is an evoked response in the cricopharyngeus muscle but not in the inferior constrictor. And so, for some reason, these two muscles are physiologically different.[1]

If the constrictor muscles become paralyzed on one side, the atrophic musculature simply balloons out on deglutition, allowing saliva, ingesta or barium during examination, to fill the pyriform sinus and from time to time to spill over into the trachea. The paralyzed pharynx never quite empties.[2]

This entire system, of course, can go wrong from paralysis of any of the posterior cranial nerves, whether from toxins, chemicals, injuries or circulatory accidents. One of the problems that we sometimes encounter in hospital practice is the patient with a vascular disorder of the brainstem who simply cannot swallow, and who floods his airway on attempted deglutition. I have asked Dr. Glenn to say a few words to us about that.

DR. WILLIAM GLENN: In the course of studying patients with ventilatory insufficiency due to central alveolar hypoventilation who might be candidates for diaphragm pacing we have encountered 13 patients with brainstem lesions who have presented a syndrome characterized by three life threatening respiratory complications: 1) central hypoventilation, 2) upper airway obstruction, and 3) dysphagia associated with aspiration pneumonitis.[3]

The neurologic diagnosis established in these patients on admission to Yale New Haven Hospital was brainstem stroke in five cases, posterior fossa neoplasm in three, meningoencephalitis in three and arteriovenous malformation and syringobulbia in each. Neurologic evaluation revealed focal pontine involvement, focal medullar involvement, and bilateral long and corticospinal tract involvement in the majority of the cases. All patients had had one or more episodes of respiratory arrest frequently followed by cardiac arrest prior to admission to Yale-New Haven Hospital. Following admissions all patients were shown to have central alveolar hypoventilation with episodes of central apnea during sleep. A ventilatory response study indicated decreased or absent response to hypercapnea

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A Panel Discussion at Surgical Grand Rounds, Yale-New Haven Hospital, June 23, 1979.

The participants in the conference were the following: ARTHUR BAUE, M.D., Donald Guthrie Professor and Chairman, Department of Surgery; WILLIAM GLENN, M.D., Charles W. Ohse Professor of Surgery, Section of Cardiothoracic Surgery; JOHN A. KIRCHNER, M.D., Professor of Surgery and Chief, Section of Otolaryngology; HAROLD R. PILLSBURY, III, M.D., Assistant Professor of Surgery, Section of Otolaryngology; CLARENCE SASAKI, M.D., Associate Professor of Surgery, Section of Otolaryngology; all are from Yale University School of Medicine.

and hypoxia. Five patients' airway needed to be kept open with a tracheostomy tube. In four other patients upper airway obstruction was observed only during sleep. Aspiration pneumonitis was a recurrent problem in most patients and necessitated antibiotic coverage almost constantly. One patient developed a lung abscess and empyema requiring drainage.

Treatment. All patients were treated for central hypoventilation by diaphragm pacing with one hemidiaphragm paced in eight patients and both hemidiaphragms paced in five patients. A tracheostoma was maintained in all patients for the relief of upper airway obstruction or for the removal of secretions. A gastrostomy was performed in 10 patients for feeding and to minimize tracheal aspiration. Three patients with severe tracheal aspiration and repeated attacks of aspiration pneumonitis had surgical closure of the larynx with complete elimination of aspiration. Cricopharyngeal myotomy for the treatment of dysphagia was carried out in two patients and was successful in one. One patient who was discharged from the hospital after Teflon injection of one paralyzed vocal cord to improve phonation died of massive aspiration during sleep despite a tracheostoma and gastrostoma and emptying of the stomach prior to bedtime.

In summary, three life threatening respiratory complications were encountered in patients surviving a diffuse brainstem lesion: central alveolar hypoventilation, upper airway obstruction and aspiration pneumonitis. A surgical plan for managing these consists of diaphragm pacing to correct hypoventilation, tracheostomy for bypassing the upper airway obstruction, gastrostomy for bypassing the impaired structures for swallowing and surgical closure of the larynx to prevent uncontrollable aspiration.

DR. JOHN KIRCHNER: Dr. Clarence Sasaki will present our experience with surgical closure of the larynx.

DR. CLARENCE SASAKI: The larynx serves three basic functions in man. In order of functional priority, these include 1) protection of the lower airway, 2) respiration, and 3) phonation. In certain diseases resulting in major loss of protective function, pulmonary contamination may become life-threatening and, as Dr. Glenn mentioned, a method of laryngeal closure which effectively prevents aspiration may be life-saving.

A number of surgical techniques have been devised to separate the upper respiratory from digestive tracts and each technique has met with diverse success. As you know, a cuffed tracheostomy tube may temporarily control aspiration, although its prolonged use invites pressure injury to the esophagus and to the trachea. In 1972, Habal described a method of glottic closure using local tissue from the epiglottis.[4] In 1975, Lindemann described a diversion procedure wherein substances from the upper digestive system could be routed into the upper esophagus through the larynx by an end-to-side anastomosis.[5] In 1975, Montgomery described his glottic closure.[6]

Let me describe a patient who recently presented with a severe form of Parkinsonism, total incoordination and spasticity of the pharyngeal musculature, chronic aspiration, and weight loss. Chest x-ray on admission to the VA Hospital showed massive aspiration pneumonitis for which a tracheostomy was eventually performed. In subsequent weeks, chest films showed an evolving lung abscess. The barium swallow showed no esophageal abnormality; gross aspiration was seen, although the patient had an intact cough reflex. With tracheostomy in place, the patient continued aspirating. At this point, laryngeal closure was considered to be life-saving. I would like to describe a new technique for laryngeal closure, developed with Dr. Kirchner and Dr. Glenn, a technique which is conceptually simple and essentially foolproof.

The larynx is approached through a horizontal skin incision and skin flaps are raised deep to the platysma muscle to expose the thyroid cartilage. The cartilage is then split in the midline, using an oscillating saw. This then exposes the true and false vocal cords and posterior commissure of the larynx. The mucous membrane of the laryngeal ventricle is next removed, resulting in a glottis which is denuded circumferentially. The free edges of both false cords and true cords are undermined, and the false cords are approximated with 4-0 Dexon in a first layer of closure. A superiorly based sternohyoid muscle flap is routed through the thyroid notch to fit into the posterior commissure of the larynx. The leading edge of this muscle is anchored to the interarytenoideus muscle in the midline posterior commissure before the free edges of the true vocal cords are brought into apposition below this, in a third layer of closure. This viable muscle flap serves a dual function. On the one hand, it obliterates a large dead space created by the apposition of the ventricular concavities and, on the other hand, three rather than one layer of closure are accomplished without tension. The thyroid alae are then reapproximated with several absorbable sutures and the wound is closed over a Penrose drain. It has been our practice to start our patients on oral feedings about 7 to 10 days postoperatively.

Five patients have now undergone the surgical closure of the larynx, using the technique described. No revision surgery was necessary in any patient over a six-month period of follow-up, closure being completely effective in all cases using the method described.

This is a typical postoperative barium swallow demonstrating contrast now entering the esophagus without tracheal contamination. As in Montgomery's far greater experience, no patient recovered from the underlying disease process necessitating surgical closure of the larynx. Nevertheless, it is theoretically possible to reverse surgical closure, should sufficient neuromuscular function return in any given patient. I think that, in Dr. Glenn's patients especially, this procedure has been particularly helpful.

DR. JOHN A. KIRCHNER: The cricopharyngeus muscle acts as a sphincter at the top of the esophagus. When this muscle does not open at the exact time that it should or when its resting pressure is elevated, dysphagia may result. It is sometimes necessary in patients who have a serious disorder of the swallowing mechanism to cut the sphincter at the top of the esophagus. As Dr. Glenn just described, we have done this in a couple of patients. It's not always successful and I have asked Dr. Pillsbury to review this procedure and to give us a little background for its use.

DR. HAROLD PILLSBURY: The cricopharyngeus muscle functions as an upper sphincter of the esophagus which, under normal conditions, maintains a state of tonic contraction. That's important to remember because when the swallowing mechanism is initiated and the bolus of food passes through the hypopharynx and into the esophagus, the cricopharyngeus relaxes, allowing the bolus to pass. Several investigators have studied the neurophysiology of the cricopharyngeus and have demonstrated both sympathetic and parasympathetic influences on its activity. It is reasonable, therefore, to suspect that intracranial lesions can cause cricopharyngeal achalasia by interruption of the parasympathetic supply. Table 1 demonstrates a number of neuromuscular disorders that can lead to this condition. In 1950, cricopharyngeal achalasia was demonstrated by Asherton to represent failure of relaxation at the entrance of the esophagus.[7]

The patient with cricopharyngeal achalasia initiates swallowing in a normal manner, the bolus being moved by the mouth and tongue into the pharynx. When the bolus reaches the cricopharyngeus the sphincter does not relax and repeated swallows are then made in an attempt to force the bolus into the upper esophagus. At this point, after numerous attempts at swallowing, the patient aspirates and may experience nasal reflux. This is followed by choking, coughing and gagging.

Table 1[8]

ETIOLOGY OF CRICOPHARYNGEAL ACHALASIA

- Idiopathic
- Myoneural function deficit
  - Myasthenia gravis
- Neural defect
  - Cerebral palsy
  - Amyotrophic lateral sclerosis
  - Syringobulbia
  - Poliomyelitis
  - Posterior inferior cerebellar artery syndrome
  - Prematurity
  - Meningomyelocele, hydrocephalus and Arnold-Chiari
- Muscular abnormality
  - Dermatomyositis and polymyositis
  - Systemic lupus erythematous
  - Muscular dystrophy
  - Acrosclerosis
  - Thyrotoxic myopathy
  - Myopophyria
  - Paroxysmal hemoglobinuria
  - Tetanus
  - Werding-Hoffman disease

Cricopharyngeal myotomy is usually performed on the left side of the neck and divides the muscle from the inferior constrictor down to the esophagus as it enters the chest. Because the cricopharyngeus is a sphincter-like muscle, it is necessary to cut only one side. As Drs. Kircher and Glenn both mentioned, this operation is not universally successful, usually because the patient in whom the operation is proposed, has other problems that cause ineffectual swallowing.

DR. JOHN A. KIRCHNER: Whether the muscle is actually in a condition of nonrelaxation or whether it does not relax at exactly the right moment is of little consequence. If you cut the muscle, a patulous opening into the esophagus is produced so that split-second timing is no longer needed.

The next topic, Zenkers Diverticulum, is closely related to cricopharyngeal achalasia and will be presented by Dr. Sasaki.

DR. CLARENCE SASAKI: Occurring most often in middle-aged men, the Zenker's diverticulum often remains asymptomatic for many years. A gurgling sensation while drinking may be the first sign of such an abnormality. As the disease progresses, the patient may become increasingly dysphagic, due to partial obstruction of the cervical esophagus as the lumen of the esophagus is compressed by the expanding diverticulum. In addition, aspiration may occur while the patient is eating; more often, nocturnal aspiration may be accomplished by severe spasms of coughing which can lead to acute and chronic pulmonary infection.

Regardless of the exact size of its development, a Zenker's first projects posteriorly and then to the left in the space between the prevertebral fascia and the pretracheal fascia. The precise reason for this protrusion to the left is not known.

Cricopharyngeal spasm, as Dr. Pillsbury has just mentioned, may also be noted in patients with Zenker's diverticulum.

Since solid food may collect in a very large sac, the patient is given a liquid diet for a day or two before operation. Although many surgeons recommend the use of the preoperative antiseptic gargles, it has not been our practice to do this. It is ideal but not always possible to insert a nasogastric feeding tube prior to the operation, since, as you know, the tube invariably enters the diverticulum rather than the lumen of the esophagus. Therefore, it has been our practice to insert a nasogastric tube after the patient has been put to sleep.

There are as many ways to operate on a Zenker's as there are to perform a tympanoplasty. In 1958, Dohlman advocated a simple endoscopic procedure; the cricopharyngeus muscle is divided intraluminally by electrocautery through a specially-developed double-lipped laryngoscope which straddles the septum between the esophagus and the diverticulum. The septum here is simply electrocoagulated.[9]

After this procedure, trapped secretions no longer overflow into the larynx because the opening of the residual sac is well below the cricopharyngeus muscle. However, it is of some concern to us that this procedure carries a very high risk of mediastinal contamination; for this reason, it is avoided today.

Belsey's operation consisted of a diverticulopexy in which a vertical extramucosal myotomy is extended for several centimeters below the neck of the sac. The sac is then simply suspended to the prevertebral fascia, with the neck inferior to the tip of the pouch. In this way, the sac no longer serves as a reservoir for secretions and swallowed matter.[10]

For most of us, one-stage diverticulectomy has been the preferred treatment. A nasogastric tube is inserted and the pouch is packed with Betadine-saturated gauze. The diverticulum is approached through a horizontal neck incision, one finger breadth above the clavicle on the left side. This incision is carried through the platysma muscle and the sternomastoid is retracted laterally. This exposure allows sectioning of the omohyoid muscle, usually running across the field, thus facilitating exposure of the lateral surface of the thyroid gland. The carotid sheath, along with the ansa hypoglossi, is retracted laterally. The posterior border of the left thyroid cartilage may then be rotated anteriorly to facilitate exposure of the Zenker's. The sac is freed up with a Kitner dissector and the neck of the sac transected. The esophagus is repaired in two layers.

If we believe that the cricopharyngeus muscle is important in the etiology of Zenker's diverticulum, a cricopharyngeal myotomy should be performed. It is, of course, important not to section the inferior constrictor muscle during myotomy, since this could aggravate the patient's symptoms by allowing the pyriform sinus, located above the sphincter, to dilate, acting as another reservoir for liquids which might again contribute to the patient's aspiration. Following cricopharyngeal myotomy, the wound is closed over a Penrose drain. It has been our practice to institute antibiotics pre- and postoperatively, and nasogastric tube feedings are used until the patient is started on oral feedings by the fifth or sixth postoperative day.

Some authors have reported a recurrence rate up to 75% when cricopharyngeal myotomy is omitted as part of the operative procedure. We feel, therefore, that myotomy is a mandatory and integral part of this operation. It is also important to note that the incidence of carcinoma in Zenker's diverticula has been reported in twenty cases to date, a statistic which may be reflected in the fact that one-stage diverticulectomy rather than the Belsey repair is at present the most widely preferred and performed operation for Zenker's diverticulum.

DR. JOHN A. KIRCHNER: The protective action of the cricopharyngeus is evidenced by the nonspecific laryngeal symptoms occurring in patients with gastroesophageal reflux. These symptoms, including recurrent laryngitis and forcible clearing of the throat may be due to laryngeal spillover, particularly during sleep. Dr. Baue will discuss some of these relationships.

DR. ARTHUR BAUE: First, I would like to emphasize several points that have been made by Dr. Sasaki and Dr. Kirchner about the stages of development of a Zenker's diverticulum. They, of course, must begin as a very small pouch and there are no symptoms at that point. As the pouch enlarges, it begins to hang down and this is the primary reason for the development of symptoms. It's not the pouch, it's not the bulge, it's the pulling down when the entrance into the pouch is no longer in the vertical plane. The symptoms of gurgling, dysphagia and other problems occur when the plane of entrance into the pouch becomes horizontal. At this time a nasogastric tube or an esophagoscope will enter the diverticulum and not pass down the esophagus. The technique that Dr. Sasaki suggested of packing the diverticulum initially is a good one when it is approached operatively.

Esophageal diverticula occur in two places proximal to the sphincters and they are probably produced by some functional disorder of the sphincter whether it be spasm or achalasia. If you encounter a classic Zenker's diverticulum, you should look distally because there is often a sliding hiatus hernia. Oftentimes, however, when a Zenker's diverticulum reaches a large size the small hiatus hernia, reflux and esophagitis are forgotten because they are less of a problem than the symptoms of the diverticulum.

Hunt, Connell and Smiley studied the relationship of the cricopharyngeus to the distal esophagus. Manometric study in patients with gastroesophageal reflux as their primary problem showed an elevation of the cricopharyngeal sphincter pressure to about twice normal (14 to 32 cm. H_2O). Those patients who had cervical dysphagia as described by Dr. Pillsbury had pressures of 37-38 cm. H_2O. Those patients however, who had distal esophageal strictures due to reflux, had low cricopharyngeal pressures (12-14 cm. H_2O-normal or low normal pressures). This suggested the possibility that a stricture protected the proximal esophagus and then the cricopharyngeus pressure relaxed. Of importance were 5 or 6 patients in whom cricopharyngeus pressure was measured before and after repair of a hiatus hernia. They found that the pressures went from a high level—25-30 cm H_2O before repair down to levels of 20 or 21 after repair.[11] This certainly suggests that the cricopharyngeus in the presence of free gastroesophageal reflux, forms a protective mechanism to prevent reflux into the throat and aspiration. This protective mechanism would be helpful for patients with reflux when they are lying down and sleeping. This raises the question as to what should be done for the patient who has both a Zenker's diverticulum and free gastro-esophageal reflux. In this situation would a cricopharyngeal myotomy (along with excision of the diverticulum) lead to problems with aspiration.

My approach to a Zenker's diverticulum is based on the work of Ronald Belsey.[10] This is to simply mobilize the diverticulum, upend it, suture it upside down to the prevertebral fascia and then do a vertical myotomy of the cricopharyngeus muscle. This gets rid of the problem and avoids an excision and possible fistula. I believe that the myotomy is mandatory.

Finally, there is another form of disordered motility I would like to discuss. This is diffuse spasm of the esophagus which is associated with a small hiatus hernia in practically all cases and with problems of reflux. This suggests then the very real possibility that reflux along with a hiatus hernia does indeed result in disorders of motility. In diffuse esophageal spasm there are uncoordinated contractions. These disorders are probably related. With cervical dysphagia as described by Dr. Pillsbury the distal esophagus should be studied to determine whether there is a sliding hernia, whether there is reflux and then decide which problem might be attacked first or in what sequence. Secondly, with a Zenker's diverticulum be aware of the distal esophagus and of a sliding hernia reflux. One must decide whether or not in those circumstances the cricopharyngeus is, indeed, performing a safety valve function in order to prevent reflux and aspiration.

Questions, Comments, Discussion

Dr. Kirchner: Dr. Touloukian, do you encounter Zenker's diverticula in children?

Dr. Touloukian (Chief, Section of Pediatric Surgery): In children there is a completely different set of problems and fortunately, Zenker's diverticulum has not been one of them. Our problems usually begin in the thoracic esophagus.

Dr. Glenn: One of the patients with brainstem lesions had a so-called spasm of the cricopharyngeus muscle and in this patient, a Zenker's diverticulum eventually developed.

Dr. Baue: I've not had experience with patients with documented cricopharyngeal dysphagia which responded to repair of a hiatus hernia and an antireflux procedure. Do you have any information on this?

Dr. Pillsbury: P.S. Hunt and his coauthors showed that cricopharyngeal resting pressures were decreased by 20 cm. H_2O or more after repair of a hiatus hernia in five of their nine subjects tested before and after surgery.

Dr. Kirchner: Thank you. We can continue the discussion over coffee and doughnuts in the Surgical Seminar Room.

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Inside Medicaid

CLAIR M. CALLAN, M.D.

Medicaid. The name alone can arouse many different emotions among physicians—anger, frustration, resignation, indignation and others. Started by Congress in 1965 to provide medical aid and care for indigent people with medical disability, it had an initial budget of $67 million. Since then the program has grown by leaps and bounds to a staggering $600 million budget for this year, and there is no end in sight.

In Connecticut the program is frequently misunderstood by both recipients and providers. Contrary to popular belief it is not a financially limitless program able to provide and pay for every procedure and item needed by a recipient. Two factors determine what services can be provided. First, the federal government grants funds that are matched in amount by the state for medical services provided by a medical provider or performed under the supervision of a physician. Second, these services must also be included in the state plan for health care. Each year the state Legislature decides what will be included in the state health care plan. State plans vary from state to state; this leads to considerable difference in the Medicaid programs among different states.

Many physicians in Connecticut have expressed negative rather than positive attitudes toward the Medicaid program. A primary complaint centers around inadequate compensation for medical services. But there is little Medicaid can do about that. Fees paid for services may not, by federal regulation, exceed those paid by Medicare for similar services. In addition the relative value scale which assigns a certain value relative to other procedures was established in 1968. There have been no substantial changes in the scale since that time. The Department of Income Maintenance (DIM) administers the Medicaid program for the State of Connecticut. Many physicians are unaware that the department does not set fees for its programs. It can only advise the amount to be reimbursed to physicians for services. Approval must come from the State Office of Policy and Management (OPM) which is a separate department over which the DIM has no control. It, not DIM, establishes fee schedules and DIM is well aware that the fees paid physicians in the Medicaid program are low in most instances when compared with usual and customary fees.

Each year when the following year's DIM budget is prepared, a request is submitted to OPM for increase in physicians' fees. In each of the past three years the request has been for 10% increase. This request is submitted to the legislature which in turn determines whether or not an increase will be granted and how much the increase will be. If a raise is agreed upon, DIM then consults with the Medical Liaison Committee of the Connecticut State Medical Society as to where the increase should be. Two years ago office and hospital visits were apportioned the major portion of the money available. Last year there was no increase; this year surgical procedures will have their unit value increased by 1 unit, and some new procedures have been added to the list, e.g., cystometrograms and graduated colonoscopies.

What can a physician dissatisfied with the present fee schedule do? The most effective method for increasing payment is for a physician to contact his legislator and inform the legislator of fee inadequacies. No matter how much pressure DIM exerts for an increase it cannot compare with force exerted by the actual providers of care, particularly when they

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are constituents who can express their views at the ballot box.

Delay in payment is another cause for concern among providers. Let me explain how delays may occur. When a physician's bill arrives in the DIM office, it is handled by a clerk with no medical training who feeds the data into a computer. If a bill does not contain all necessary information it will be rejected by the automated system because the clerk will not be able to program all necessary information. It is essential that all codes and numbers asked for be completed on the form if prompt payment is to be made. When everything is correct a "clean" bill can be processed and paid within 30-40 days. If a bill is rejected by the automated system it is "kicked out" for manual review which takes longer.

Many problems could be avoided if physicians ensured that their office staff complete the bills accurately. One of the biggest problems centers around correct procedure codes. When a certain code is used, that is the procedure paid for, whether or not it is the one provided for the patient. The computer only processes numbers which are fed to it from the bill. Sometimes when a physician writes to complain of inadequate payment for a service, it is determined upon review that an incorrect procedure code was used. If there is underpayment an adjustment in payment can be made by applying the correct code. But this takes time.

Procedures for which the department will pay are listed in the Relative Value Scale book, the "Green Book." A procedure not listed in that book cannot be paid for. From time to time a new procedure is added. This happens when additional money is made available by the Legislature. Procedures to be included are cleared through the Connecticut State Medical Society Liaison Committee. When they are approved by both DIM and the Liaison Committee, the procedures must then be approved by the Office of Policy and Management before they are included in the fee schedule. If a physician would like an excluded procedure covered, the physician should submit application to the Medical Liaison Committee. All procedures must also fall within the guidelines established by the federal Department of Health and Human Services (formerly Health Education and Welfare).

Some procedures such as psychiatric therapy must be authorized in advance, or payment will not be made. Many physicians are reluctant to go through the routine of obtaining prior authorization, preferring to treat the patient for nothing or not to treat the patient at all. Prior authorization does not have to be a problem if the correct procedure is followed, but it does entail paper work of which there is an over abundance already. The Department is hoping to establish a provider relations section in the not too distant future. A function of this section will be to schedule workshops which will cover the mechanics of completing forms properly. These workshops will be held in several locations around the state. At present there is no definite date for implementing this section.

A frequently overlooked service that requires prior authorization is out-of-state treatment. No Medicaid recipient may receive services outside Connecticut unless this has been given prior authorization by DIM. A referring physician must contact the Department to request the authorization. This is generally in writing, but in emergencies verbal permission may be granted before the paper work can be completed. Authorization cannot be granted if the service requested is available in Connecticut, unless the physician can adequately document the reason for the out-of-state referral. Lack of prior authorization has caused some patients to be turned away from out-of-state hospitals after making a long trip. This is a distressing experience for everyone—the patient, the physician and the hospital, and DIM.

During the past four years a few physicians have received letters from the Department informing them that they have billed inappropriately for services and asking for a refund. This has caused alarm and anger. Several physicians maintain that the department should have withheld payment before it was made if the bill was not correct. While there may be some validity to that argument, presently there is no mechanism for prepayment audit. Postpayment audit is the only means whereby payments can be monitored. The majority of physicians who question the Department's request for refund can come to amicable agreement or compromise. The same is true for any problem a physician may have with the State. In most cases all that is necessary to resolve the problem is a phone call or a letter—the department is always willing to communicate with providers.

The Medical Liaison Committee is a committee established by the Connecticut State Medical Society. Members include representatives from most of the medical specialties. The committee meets regularly with members of the staff of DIM to discuss areas of common interest and concern. It helps to maintain good rapport between the department and CSMS. The department is committed to keeping providers in the program. Staff members are always willing to meet with physicians to discuss problems as they arise, or to help in any other way.

In summary, the Department of Income Maintenance is not always as obstructionist as most physicians believe. Nor are physicians as difficult to deal with as the Department sometimes believes. Both factions can and should work together for the benefit of the patient-population.

American Medical Association
Connecticut State Medical Society
and the
New Haven County Medical Association, Inc.
v.
Federal Trade Commission

DECISION OF THE UNITED STATES COURT OF APPEALS

For the Second Circuit: October 7, 1980

Mansfield and Timbers, *Circuit Judges* and Bonsal, *District Judge*

Bonsal, *District Judge* |with Timbers, *Circuit Judge*|

The American Medical Association ("AMA"), the Connecticut State Medical Society ("CSMS"), and the New Haven County Medical Association, Inc. ("NHCMA") petition for review of a cease and desist Order issued by the Federal Trade Commission ("FTC") against AMA on October 12, 1979. The Order requires AMA to cease and desist from promulgating, implementing, and enforcing restraints on advertising, solicitation, and contract practices by physicians and on the contractual arrangements between physicians and non-physicians. The FTC found that ethical standards issued by AMA were in violation of Section 5 of the Federal Trade Commission Act.

The Facts

AMA is an Illinois not-for-profit corporation first incorporated in 1897. Its membership is comprised of physicians, osteopaths and medical students, but most of its members are practicing physicians. As of December 31, 1974, 52.6% of the licensed physicians in the United States were members of AMA. AMA's legislative body is its House of Delegates. Enactments of the House of Delegates become the official policy of AMA. In 1957 the House of Delegates approved the "Principles of Medical Ethics" consisting of a preamble and ten paragraphs. Interpretation of the "Principles of Medical Ethics" is made by AMA's Judicial Council, a committee of the House of Delegates, and the decisions of the Judicial Council are set forth in the AMA publication, *Opinions and Reports.* The Judicial Council also is responsible for reviewing adjudications of state societies.

CSMS is the state medical society in Connecticut. A number of state medical societies originally formed AMA and membership in a state medical society is a condition to membership in AMA. 82% of Connecticut physicians are members of CSMS.

NHCMA is a local medical association. 71% of New Haven physicians are members of NHCMA. A New Haven physician must be a member of NHCMA in order to become a member of CSMS.

On December 19, 1975 the FTC filed a complaint against AMA, CSMS, and NHCMA charging them with restricting the ability of their members to advertise for and solicit patients and with interfering with the ability of their members to engage in contractual relationships with non-physicians. CSMS and NHCMA were included in the complaint on the ground that the state societies and local associations follow the lead of AMA and because the FTC believed that there was a conspiracy between AMA and the state societies and local associations to restrict competition among physicians through ethical limitations on advertising, solicitation and contractual relationships. Such restriction, in the view of the FTC, violated Section 5 of the Federal Trade Commission Act.

The FTC held hearings between September 7, 1977 and May 5, 1978. On November 13, 1978, the administrative law judge, Ernest G. Barnes, issued his Initial Decision finding that the ethical practices complained of violated Section 5 of the Federal Trade Commission Act. On appeal of the administrative law judge's decision to the FTC, the Commission affirmed and issued its Opinion and Final Order on October 12, 1979. The Final Order requires AMA to cease and desist from promulgating, implementing and enforcing restraints on advertising, solicitation and contract practices by physicians and on the contractual arrangements between physicians and non-physicians. Exception is made with respect to "false or deceptive" practices, and the Order provides that nothing contained therein prohibits AMA from

> "formulating, adopting, disseminating to its constituent and component medical organizations and to its members, and enforcing reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representations, that would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act, or with respect to uninvited, in-person solicitation of actual or potential patients, who, because of their particular circumstances, are vulnerable to undue influence."

The Order also requires AMA to disassociate itself from any state or local society that violates the terms of the Order.

Preliminary Issues

Two preliminary issues have been raised by the petitioners: (1) that the FTC lacks jurisdiction over the petitioners, and (2) that Chairman Michael Pertschuk should have been disqualified because he had demonstrated through his public statements that he had prejudged key issues in the proceeding. [The court sustained the opinion of the FTC as to preliminary issues.]

Jurisdiction over Petitioners [omitted]

Disqualification of Chairman Pertschuk (omitted)

Liability

At the time the FTC filed its complaint in this action on December 9, 1975, AMA's authoritative interpretation of the ethical restraints that are the subject of this action were contained in the 1971 edition of *Opinions and Reports.* Both the administrative law judge and the Commission detailed numerous examples of applications of the ethical restraints evidencing an anticompetitive purpose and effect. These included restrictions upon the dissemination of price information, bans upon advertisement of individual physicians' services and alternative forms of medical care, and restraints upon particular forms of advertising. The Commission concluded that this evidence "is susceptible to no interpretation other than that ethical principles of the medical profession have prevented doctors and medical organizations from disseminating information on the prices and services they offer, severely inhibiting competition among health care providers." The Commission further found that AMA's contract practice restrictions had the purpose and effect of restraining competition by group health plans, hospitals, and similar organizations, and restricted physicians from developing business structures of their own choice. *Id.* at 41-43. Based upon our own review of the record, we conclude that these findings are substantial evidence.

Petitioners contend that the ethical guidelines are merely to assist the state societies and the local associations; in other words, that they are advisory only. They point out that no formal action has been taken by AMA in these matters since 1955 in the appeal of Ben E. Landess where Dr. Landess was charged with "the indirect solicitation and procurement of patients by advertising." Dr. Landess was the Medical Director of the Jamaica Medical Group, which had a contract with the Health Insurance Plan of Greater New York, Inc. ("H.I.P."), which offers a form of prepaid medical coverage in the State of New York. H.I.P. advertises directly to the public. The Judicial Council of AMA adopted the report of the Queens County Medical Society that no action be taken against Dr. Landess. The Judicial Council went on to say that since the quality of its advertising is not in issue and "since Dr. Landess had nothing to do with the preparation or distribution of the advertising, it is our opinion contrary to that of the state and county medical societies that the conduct of Dr. Landess does not violate the ethic relating to solicitation and advertising."

In any event, the issue here is not whether AMA has specific power or authority over the state societies and local associations or, if it has, whether it exercises it. The issue is whether these groups have acted in concert to effectuate restraints on advertising and solicitation in violation of the Federal Trade Commission Act. It is this concerted activity for a common purpose that constitutes the violation.

The record satisfies us that AMA intended and expected that the state and local medical groups would enforce the limitations on advertising and solicitation and, indeed, advised them as to how to do it. In other words, AMA limitations "provided the impetus" for the actions taken, and individual physicians "could be expected to comply in order to assure that they did not discredit themselves by departing from professional norms, and perhaps betraying their professional oaths." *Goldfarb v. Virginia State Bar,* 421 U.S. at 791 n.21.

Remedy

The Final Order of the Commission consists of six Parts, the first two being the cease and desist Orders, and the third and fourth being the notice and disaffiliation provisions. The Final Order is directed only to AMA, and not to CSMS or NHCMA.

Part I of the Order directs AMA to cease and desist from (A) restricting the advertising of services, facilities, or prices by physicians or organizations with which physicians are affiliated; (B) restricting the operation of any organization that offers physicians' services to the public, by means of representations concerning the ethical propriety of medical service arrangements that limit the patients' choice of a physician; and (C) inducing any physician or non-governmental medical organization to take any of the prohibited restrictive actions. Part I expressly excludes from its prohibitions the dissemination by AMA of reasonable ethical guidelines concerning false and deceptive advertising and solicitation.

Part II of the Order directs AMA to cease and desist from (A) restricting or interfering with the consideration offered or provided physicians in return for the sale of distribution of their professional services; (B) restricting any organization that offers physicians' services by means of representations concerning the ethical propriety of medical service arrangements that limit the patients' choice of a physician; (C) restricting participation by non-physicians in the ownership or management of such organizations; and (D) inducing physicians or any organization from taking any of the actions prohibited by Part II.

Part III of the Order requires AMA in any proceeding involving violations of its ethical standards to provide (A) reasonable notice, (B) a hearing, and (C) written findings and conclusions.

Part IV of the Order requires AMA to (A) give written notice of the Order to its members and affiliate societies; (B) provide all new members and affiliate societies with a copy of the Order for a period of ten years; (C) remove from all of its publications and policy statements any provisions inconsistent with the Order; (D) require that all affiliate organizations, as a condition of affiliation, agree to adhere to the Order; and (D) disaffiliate for one year any constituent organization that engages in any act of practice prohibited by the Order.

Post-Complaint Activities of AMA

Petitioners contend that the revisions of the ethical standards contained in the 1977 *Opinions and Reports* obviate any need to enter the Order herein. However, this does not constitute grounds for denying enforcement of an FTC order, especially since the publication of the revisions occurred "only *after* the filing of the FTC complaint." In any event, the Commission can properly find, as it did here, that the revisions were insufficient.

Additionally, it is not clear that the 1977 revisions rescinded prior ethical standards. AMA has never announced to its members or affiliate societies that the 1971 ethical standards are no longer in effect. Moreover, nothing in the 1977 version of the *Opinions and Reports* indicates that it was intended to disavow prior standards. Rather, it refers with approval to the "long standing policy of the Judicial Council on advertising and solicitation by physicians." By referring to the established policies, AMA indicated that its positions may not have changed and that the restraints, "if abandoned at all, may be resumed." Finally, it is well established law that it is within the discretion of the FTC to determine whether an order is "necessary to cope with the unfair practices found." We have determined that the FTC considered the changes and rationally assessed their significance in concluding that a cease and desist order was warranted.

On July 22, 1980, AMA's House of Delegates adopted a new version of the *Principles of Medical Ethics*. The most notable change is the removal of the ban on "solicitation" previously found in Section 5 of the *Principles*. The 1980 *Principles* instead require a physician to deal "honestly," to expose doctors "deficient in character or competence," and "to respect the rights . . . of other health professionals."

The elimination of the ban on solicitation which appeared in the 1957 version of the *Principles* reflects a significant and commendable effort to comply with the terms of the FTC order here under review. AMA does not, however, concede any legal obligation to make such changes, since it still denies any involvement in the unlawful restraints found by the FTC.

The language of the 1980 *Principles* is general and imprecise in nature. Moreover, the various written interpretations of the 1957 *Principles* previously promulgated by AMA remain in effect. In the absence of any interpretation of the 1980 *Principles* in AMA's *Opinions and Reports,* we cannot find that the FTC's claims are moot.

First Amendment

Petitioners contend that Part II of the cease and desist Order constitutes a prior restraint upon speech and impermissibly interferes with the right to freedom of association under the First Amendement. We disagree. The FTC determined that various restrictions which AMA imposed upon contract practices of physicians violated the FTC Act. These included ethical restraints upon so-called "closed panel" arrangements, upon the consideration paid physicians by health care organizations, and upon physicians' arrangements with non-physicians. By its terms, the Order applies solely to "ethical" restraints, and thus does not affect any speech or other first amendment rights except insofar as it applies to statements officially condemning contract practices. "Just as an injunction against price fixing abridges the freedom of businessmen to talk to one another about prices, so too the injunction in this case must restrict |AMA's| range of expression on the ethics of |contract practices of physicians|."

Overbreadth and Vagueness

Petitioners assert that the proviso at the end of Part I, which permits AMA to adopt "reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representations, that would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act," is overboard and vague. The proviso was inserted in the Final Order at the request of AMA because of the Commission's "conviction that the AMA has a valuable and unique role to play with respect to deceptive advertising and oppressive forms of solicitation by physicians." FTC Opinion, at 58. AMA asks that it be granted more leeway in determining what kinds of claims are deceptive and misleading without the chilling effect that the threat of fines and penalties could have on its regulation of false and deceptive advertising. The Commission recognizes the " 'special role' of organized medicine . . . [that] necessarily confers on AMA a measure of discretion to develop 'principles of conduct.' " In view of the foregoing, we will amend the proviso by inserting the words "respondent reasonably believes" so that the concluding paragraph of Part I will read as follows:

> "Nothing contained in this Part shall prohibit respondent from formulating, adopting, disseminating to its constituent and component medical organizations and to its members, and enforcing reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representation, that *respondent reasonably believes* would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act, or with respect to uninvited, in-person solicitation of actual or potential patients, who, because of their particular circumstances, are vulnerable to undue influence." (modification emphasized)

Additionally, petitioners contend that Part II-A of the Order requires AMA to cease and desist from "advising on the ethical propriety of, or interfering with the consideration offered or provided to any physician in return for the sale, purchase or distribution of his or her professional services." AMA points out that this provision is so broad as to impinge upon valid activity such as professional peer review of the fee practices of physicians. In apparent recognition of this and mindful of Judge Wisdom's caveat that an FTC order "should not be drawn so broadly that it will cover legitimate practices," the Commission requests us to modify clause II-A of the Order to add the words "in any contract with any entity that offers physicians' services to the public" following the word "physician." This modification clarifies the meaning of the Order, especially in light of the administrative record herein. However, in view of AMA's contention in its reply brief that the Order is still overbroad, we will further modify the Order by adding the words "except for professional peer review of fee practices of physicians." Thus, the clause, as modified, will read:

> "Restricting, regulating, impeding, advising on the ethical propriety of, or interfering with the consideration offered or provided to any physician *in any contract with any entity that offers physicians' services to the public,* in return for the sale, purchase, or distribution of his or her professional services, *except for professional peer review of fee practices of physicians . . ."* (modification emphasized)

The Disaffiliation Provision

Part IV of the Order requires AMA to disaffiliate for one year any state or local medical society that engages in acts or practices that would violate the Order if engaged in by AMA, and requires as a condition to affiliation that the state and local societies agree to adhere to the provisions of the Order. Petitioners contend that this violates due process. The Order does not violate AMA's right to due process since it bears a reasonable relationship to the unlawful practices found to exist. The Commission "must be allowed effectively to close all roads to the prohibited goal, so that its orders may not be by-passed with impunity," by the state and local medical societies.

The Final Order of the FTC is MODIFIED as indicated herein. As so modified, the Order is ENFORCED.

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Mansfield, *Circuit Judge* [Dissenting]:

I respectfully dissent for the reason that the steps promptly taken by the American Medical Association to modify and up-date its ethical standards after the Supreme Court's decision in *Goldfarb v. Virginia State Bar*—revisions that were commenced prior to the FTC's initiation of the present proceeding—satisfy me that the Commission proceeding has been unjustified, unnecessary, and a waste of administrative and judicial resources. In essence the Commission's order, as somewhat watered down by the majority opinion here, is based on outdated facts that long since have ceased to exist. It merely requires the Association to do what it is doing anyway and prohibits it from doing what it is not doing. Notwithstanding the mootness of the issues and the absence for years of "a reasonable likelihood that the past wrong-doing will recur," the Commission insisted on pressing for its pound of flesh. In my view the FTC is engaged in the futile business of beating a dead horse.

Before proceeding to the merits I agree that the Commission had jurisdiction over the subject matter. However, I cannot agree with the majority that such jurisdiction exists whenever the business interests of associations are "secondary to the charitable and social aspects of their work," which would confer jurisidiction whenever a non-profit organization serves *any* business interest. Although trade associations, which are primarily vehicles for the pecuniary gain of their members, fall within the definition of § 4 of the Act, professional organizations were not discussed in the legislative history of the statute and jurisdiction over non-profit organizations was denied by Congress. In view of this history the appropriate test in my view would be whether the association engages in a substantial amount of activity for the pecuniary gain of its members. Where its activities designed to help its members' economic status are purely incidental or *de minimis* in comparison with the organization's nonremunerative activities, jurisdiction does not exist.

However, the Association's business-related activities are sufficient to bring it within the FTC's jurisdiction under even this quantitative test. Its lobbying efforts and advice on office and business practices—all designed to furnish assistance of economic value to its members—form a substantial part of its activities. The Association therefore bears a closer resemblance to a trade organization than to a strictly fraternal, scientific or charitable association.

I also agree, although somewhat *dubitante,* that prior statements of Chairman Michael Pertschuk of the Commission, who participated in the oral argument, deliberations and decision in this case, did not call for his recusal or disqualification on the ground that he had "in some measure adjudged the facts as well as the law" of the case. Although an FTC Commissioner may form and express general views about law and policy, Chairman Pertschuk's statements here came extremely close to the line of prejudgment. For instance, in a prepared statement dated October 10, 1977, which was not given, he said:

> "While it would probably be excessive to say that the fox is guarding the chicken coop, it is undeniable that a great many critical judgments in this field are being made by persons with a direct economic stake in particular outcomes .... The vast majority of physicians and their organizations sincerely believe that they are acting in the public interest. Yet this is not enough. To be genuinely well served, the public must have assurance that those in control are responsive to consumer needs."

Although this and similar statements have the earmarks of prejudgment, I am willing in this instance to give the speaker the benefit of the doubt.

Turning to the merits, it was not until the Supreme Court's June 16, 1975, decision in *Goldfarb,* that the Association knew that it was subject to the provisions of the Sherman Act. It is undisputed that it promptly instituted on its own a review of its *"Principles of Medical Ethics,"* which had been approved in 1957 by its House of Delegates, and its interpretations of these principles for its members, which had been published in 1971 in a statement of *Opinions and Reports.* The purpose (and in my view, the effect) of the review was to bring its activities in compliance with antitrust requirements. The review led to the Association's issuance on April 9, 1976, of a revised statement of the Principles and in March, 1977, of a new edition of the *Opinions and Reports.* It is clear that the Association was already engaged in its bona fide revision of its ethical standards when the Commission instituted the present proceeding on December 19, 1975, and that the FTC had not yet taken any irrevocable action in the case before the revision was completed. (The ALJ's Initial Decision did not issue until November 13, 1978.) Moreover, although the Association's 1971 publication of *Opinions and Reports* had contained some anti-competitive features that were objectionable from an antitrust law standpoint, these provisions had not been generally enforced; indeed, they were hardly enforced at all. For these reasons I believe that the Association should be judged by its 1976 and 1977 revised principles and interpretations rather than by the earlier ones.

The effect of the revised principles and interpretations was to revoke and rescind the earlier ones. There is no evidence from which it might reasonably be inferred that the Association, its affiliates and members would not adhere to the revised principles in lieu of the earlier ones. In my view the 1976 principles as interpreted in 1977 substantially comply with antitrust requirements and overrule those prior interpretations which might have offended the Sherman Act. The new *Opinions and Reports* states that dissemination of non-deceptive information, including fee information, is ethical. "Solicitation," which is narrowly defined to cover only certain deceptive promotional devices which clearly have a significant capacity to mislead (e.g., claims intended or likely to create inflated or unjustified expectations of favorable results, self-laudatory statements implying that a physician has superior skills, and other factual misrepresentations) is properly condemned as unethical. Such restraints hardly suppress competition.

Advertising by doctors of fee information is permitted, and useful information may be published in "office signs, professional cards, dignified announcements, telephone directory listings and reputable directories." Physicians may ethically be employed on a contract basis, provided they "should not be subjected to lay interference on professional matters and that their primary responsibility should be to the patients they serve." This reasonable provision eliminates the earlier restrictions on contractual arrangements found in the 1971 *Opinions and Reports* and the 1974 Report on *Physician Hospital Relations.*

In short, a review of the 1977 *Opinions and Reports,* considered in the light of the other record evidence, demonstrates that the Association, long prior to any order in this case, had changed its ethical standards to insure reasonable compliance with the law and at the same time properly to "discourage abusive practices that exploit patients and the public and interfere with freedom in making an informed choice of physician and free competition among physicians." (AMA Statement of April 9, 1976). It is significant that in *Bates v. State Bar of Arizona,* the Supreme Court cited with approval the Association's revised standards, stating:

> "Indeed, it appears that even the medical profession now views the alleged adverse effect of advertising in a somewhat different light from the appellee. A Statement of the Judicial Council of the American Medical Association provides in part:
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> " 'Advertising—The *Principles [of Medical Ethics]* do not proscribe advertising; they proscribe

the solicitation of patients . . . . The public is entitled to know the names of physicians, the type of their practices, the location of their offices, their office hours, and other useful information that will enable people to make a more informed choice of physician.

" 'The physician may furnish this information through the accepted local media of advertising or communication, which are open to all physicians on like conditions. Office signs, professional cards, dignified announcements, telephone directory listings, and reputable directories are examples of acceptable media for making information available to the public.

" 'A physician may give biographical and other relevant data for listing in a reputable directory . . . . If the physician, at his option, chooses to supply free information, the published data may include his charge for a standard office visit or his fee or range of fees for specific types of services, provided disclosure is made of the variable and other pertinent factors affecting the amount of the fee specified. The published data may include other relevant facts about the physician, but false, misleading, or deceptive statements or claims should be avoided.' 235 J.A.M.A. 2328 (1976)."

Any possible lingering doubt about the Association's independent voluntary compliance with the law is dispelled by the adoption by its House of Delegates on July 22, 1980, of new *"Principles of Medical Ethics"* which completely eliminate the controversial former provisions attacked by the FTC despite their reasonableness as construed by the Association's *Opinions and Reports.* The new ethics code omits Section 5 of the former *Principles of Ethics* which provided that a physician "should not solicit patients" and Section 6, which specified that "A physician should not dispose of his services under terms or conditions which tend to interfere with or impair the free and complete exercise of his medical judgment and skill or tend to cause a deterioration of the quality of medical care." Thus the Commission's order deals with practices that are now ancient history rather than with the facts as they now exist. Instead of facing reality it has set up the equivalent of a "straw man" to accommodate its desire to regulate the Association.

The burden is on the Commission to show that injunctive relief is warranted, and that there is "positive proof of a reasonable likelihood that past wrong-doing will recur." The relevant proof, which in my view consists of the Association's post-*Goldfarb* activities, does not provide substantial evidence supporting a finding of liability. Moreover, since there is no evidence of likelihood that pre-*Goldfarb* activity will recur, the Commission's order in my view constitutes an abuse of discretion.

For these reasons I would deny enforcement.

THE AMA PETITIONED THE U.S. COURT OF APPEALS for a rehearing of the Oct. 7 two-to-one decision upholding a Federal Trade Commission order against the Association on physician advertising and contract practice. At issue in the case is the relationship between the government and the private citizen, the AMA said.

In the petition the AMA suggested that the rehearing be before the full court. The Oct. 7 ruling was made by a three-judge panel, one of the members of which was a district court judge filling a temporary vacancy. Joining the AMA in the petition were the Connecticut State Medical Society and the New Haven County Medical Assn.

The medical organizations noted that Judge Walter R. Mansfield in his dissenting opinion said the FTC's order "deals with practices that are now ancient history rather than with the facts as they now exist. Instead of facing reality it has set up the equivalent of a straw man to accommodate its desire to regulate the Association." This type of activity by an administrative agency "not only wastes public funds, but also discourages voluntary self-regulation by the private sector," the petition stated.

It is undisputed, the AMA said, that the Judicial Council had begun a review of the Association's position on ethics before the FTC filed its complaint in 1975. The AMA said, "Perhaps the most important question presented by this case is whether administrative agencies should respect and encourage responsible efforts by the private sector to comply with rapidly evolving legal standards and social values—or whether such efforts should be rewarded with the kind of sweeping order enforced in this case. This question far transcends the immediate facts of this case. It puts at issue the very relationship between government and private citizen in our society."

The petition urges a rehearing by the full court of appeals "so that a definitive pronouncement will be made . . . on the authority of the Federal Trade Commission in the non-profit area . . . . In the first proceeding in which the FTC has sought to regulate the ethics of a profession, the two active judges on the panel split. Particularly since the majority opinion was written by a district judge, there is no clear statement from this court on the important issues raised by this case."

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The Professional Looks at Medicine and Its Future

Dilemmas of the Decade: Medical Education and Licensure

ORVAN W. HESS, M.D.

ABSTRACT—The American Medical Association has a noteworthy history of more than 75 years of involvement in medical education since the establishment of the Council on Medical Education as a Permanent Standing Committee in 1904. The contributions of its numerous Committees have been outstanding. Some accomplishments have been the Flexner Report (1910), the Coggleshall Report (1964) and the Millis Report (1966). The willingness of the AMA to finance the maintenance of an accreditation system in the public interest has provided the perspective and stability necessary to ensure balance and direction of their efforts.

Representatives of the Council, its allied groups, and of the Government convened to review the status of the system of education and licensure of physicians and to consider perceived problems and challenges to meet the needs of the '80s. This report summarizes the comments of these speakers at the 76th Annual Congress on Medical Education.

The 76th Annual Congress on Medical Education and the Annual Meeting of the State Medical Boards were held at the Palmer House, Chicago, on April 22-26, 1980. The meetings were co-sponsored by three organizations: The American Medical Association (AMA), the Association of Hospital Medical Education (AHME) and the Federation of State Medical Boards (FSMB).

Noting that previous Congresses had provided a forum for discussion of ideas that had a great impact on undergraduate, graduate and medical education, Dr. Patrick Corcoran, Vice-Chairman of the Council on Medical Education, opened the meeting calling attention to its central theme "Dilemmas of the Decade: Medical Education and Licensure."

Rapid evolution of new knowledge and revolutionary changes in the financing of educational institutions and various components of our health care system have created special difficulties. The main topics selected for consideration were: Generalism and Specialism, Professional Perspectives, Regulation of Medicine, and Factors Influencing Medical Programs.

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The keynote speaker was *Dr. Donald Kennedy, Ph.D.* (physiology) Harvard University, member of Board of Overseers of Harvard College, now Vice-President and Provost of Stanford University. Dr. Kennedy was Commissioner of the Food and Drug Administration from 1977 to 1979.

> *"Medicine is experiencing an era of extraordinary development and a knowledge explosion at a time when high costs of health care are creating a policy crisis."*

Focusing on *Special Perspectives on Matters of Regulation,* Dr. Kennedy observed that "the rate of growth of new knowledge and new technology has everyone worried: (1) "Doctors: how to remember everything; (2) The Government: how to control and distribute health care; and (3) The People: how to pay for it."

ORVAN W. HESS, M.D., AMA Delegate, attended the Congress on Medical Education and Licensure, Chicago, 1980, and submitted this report to the CSMS Council.

He identified several problems which should be considered:

1. An oversupply of physicians exists, or soon will, throughout the nation. Studies indicate that an oversupply forces costs of medical care up.
2. Many contemporary "half-way technologies," as defined by Dr. Lewis Thomas are more costly than fully settled technologies such as vaccination.
3. There is doubt that the kind of medicine as generally practiced is improving health. "No correlation can be made between expenditures for medical care or the number of physicians per capita with an improvement in health." More biostatistical and epidemiological studies are needed to permit evaluation of cost-effectiveness on a population basis.
4. There are questions whether education is preparing doctors adequately for the practice of preventive medicine.

It is not surprising that the government is exhibiting more interest in regulation. Legislators feel the need to control costs through legislation, by limiting expenditures for health education facilities, control of technology development and research, change in third-party reimbursement policy or by shaping education through incentives and the injection of competitive choices. Current medical education, he believes, has three prominent weaknesses: (1) Inefficiency due to lack of proper articulation between basic science in undergraduate years and the clinical years of medical training. (2) Failure to make physicians aware of methods of applying population and epidemiological techniques in the evaluation of cost-effectiveness of health care, and the importance of the role of preventive measures and screening. (3) Physician participation in continuing education is still inadequate. He noted that the pharmaceutical industry annually spends more dollars than government and medicine combined ($3000/yr/doctor). He justified regulation of the drug industry on the basis of its history prior to the establishment of controls in 1961. The federal law which established the efficacy requirement (Kefauver) that a controlled clinical trial be included in the evaluation and approval of a drug has been beneficial.

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Nathan J. Stark, a member of the National Academy of Science, previous Senior Vice-Chancellor of University of Pittsburgh, now Under Secretary of Health, DHHS, Washington, D.C., spoke on *Public and Professional Perspectives.*

> *"There is a special need for close partnership between Government and the Profession in meeting our health care needs, particularly in a period of budgetary restraint."*

Sec. Stark said leaders of the nation's medical education community are in position to allocate resources which must be targeted in on the nation's most important priorities. The recent increase in inflation rate in the nation prompted President Carter to submit revisions in the 1981 budget. The economic situation changed so rapidly that the administration took immediate action. In March, President Carter submitted his new comprehensive five-point anti-inflation plan. In medicine, no cut was made in the basic essentials necessary for preserving human services. Programs like Social Security, Medicare and Medicaid, and AFDC were preserved. Head-Start and initiatives designed to aid employment of urban youth were not cut. The plan has expanded funding for Community Health Centers and the National Health Service Corp. It has supported Hospital Cost Containment Legislation and advocated HMOs to strengthen competition in the health care sector. It has suggested stronger health prevention programs. An effective partnership between Government and the Profession is necessary if we are to succeed. Funding of some good programs of professional training and biomedical research and other important programs were reduced or eliminated. The President's anti-inflation program calls for the exercise of discipline and sacrifice. Inflation *must* be fought. The plan *must* succeed and costs of health care *must* be contained.

It is felt that Biomedical research must be stabilized and a health research program maintained. This requires a university-based program with continued Federal support. The 1981 NIH research budget assures a stable 5000 new and competitive research grants and plans for funds for maintaining continued research effort. Special needs of teaching hospitals are to be taken into consideration.

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Robert Kelly, M.D., University of Minnesota, with 28 years experience in Family Practice in association with group practice arrangements, Chairman of AMA Council on Medical Service which had just completed a study of HMOs in the U.S., discussed *Practice in New Reimbursement Modes.*

> *"The increase in cost of medical care has resulted from the introduction of new government programs, new technology, increased demands by consumers and the inflationary spiral itself."*

The Health Maintenance Organization is a major alternative for medical care delivery that has aroused great interest. Dr. Kelly's Council reviewed 127 articles on HMOs and conducted 18 site visits. A full report of the findings will be available in July. There are mainly two basic structures of HMOs: (1) a *closed panel model* operating on a fixed budget with reimbursement on a capitation basis, and (2) the *IPA model* with individual physicians practicing in their offices providing services to subscribers on a fee-for-service basis. The real degree of cost-effectiveness of HMOs is still clouded because of heavy subsidy by the government funds. The jury is still out regarding cost-saving.

The Profession has shown great interest in HMOs. As a basis for consideration when choosing the type, he suggests three benchmarks: (1) disrupts the consumer the least, (2) disrupts the provider the least, and (3) provides good quality of care and good access. Disturbance of patient-physician relationship should be avoided. Patients felt that inadequate care is provided in some instances because the fixed budget affects decisions regarding management.

HMOs look promising from the economic standpoint, but this aspect is still unproven. An experimental mode is being tested on the East Coast. In this Diagnostic Related Grouping program, hospital reimbursement is based on average cost of total care related to diagnostic grouping rather than on an PAS-determined allowable length of stay. New methods of reimbursement must be carefully evaluated to be sure that they do not reduce our traditional *quality* of care.

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Norman Cousins—Member Dept. of Psychiatry and Bio-behavioral Sciences, School of Medicine, UCLA, editor of Saturday Review (35 years), author of 14 books including "The Anatomy of an Illness," Member of the Nat. Acad. of Sciences.

As the principal speaker Dr. Cousins chose to speak on the subject, *What is Soft, What is Hard?* He firmly supports the concepts expressed in the Report of the AMA Council on Education, "Future Direction of Medical Education." He noted the comment in the Surgeon-General's report that "the health of the people of the U.S. has never been better." This fact has been documented. In 1979 the death toll from some of the common killers like diphtheria, polio, T.B., small-pox, etc. had been 10,000. If the population trend had continued as in 1900, and we did not have the means we now have to combat these diseases, the deaths would have been 850,000. From that point of view the health of the U.S. people appears to be in good shape. But changes have occurred in the causes of death. The principal killers among young people are now death by accident and by murder. The single greatest cause of death among non-whites under 19 years of age is by murder.

Among unsolved health problems of the day is widespread anxiety. Last year 16 million prescriptions were written for Valium. Medical education, he thinks, has not provided enough knowledge of the cause of anxiety and the means by which to deal with the phenomenon. Nor has there been sufficient motivation of the profession to give proper attention and care for the 85% of persons going to doctors' offices with so-called self-limiting illnesses. These are areas of concern which need greater efforts toward a solution.

Fulfilling his role as an ombudsman, Dr. Cousins told several significant stories and described personal experiences of patients and their physicians which pointed up some deficiencies of the physician-patient relationship which must be corrected if doctors are to better serve the needs of society. He feels that the trend toward consumerism is now reaching the medical profession and can become an explosion which may lead to a Naderism-like war which can last many years, unless we can effect a turnabout in which the interests of the profession and the public can converge. The profession should take the lead in such an effort. In agreement with the opinions expressed in "Future Directions of Medical Education" he feels that greater emphasis should be placed in undergraduate education on the "soft" facts (biostatistics, ethics, philosophy, literature, history), than on the "hard" facts (such as biochemistry, pathology, pharmacology). In that way, he believes, the understanding of the inter-action of the forces of society and illness will be enhanced. The doctor would then be better prepared to meet the health needs of society.

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Theodore Cooper, M.D., Past Assistant Secretary of HEW; currently Dean and Provost at Cornell University Medical School, New York.

> *"The physician is being challenged as the primary driver of the system. The healer and healee are expected to look at each other in new ways. There will be more overt efforts made to redefine the roles of providers of services as we attempt to meld our technical revolution to the evolution of social and political attitudes. In planning, the profession should take the leadership and not be led along screaming."*

Dr. Cooper feels that it is obvious to the citizenry that there is confusion and skepticism that we are actually making progress. On what basis, he asks do we measure progress—more knowledge, more technology, greater longevity, decreased morbidity, giving more and better service to more people—or all of these? All too often we measure progress by relating the amount of expenditure, or the rate of scientific breakthroughs, or improvement in national mortality rates, and not by the true impact on the human condition.

It is being recognized that health of the public is often determined by factors outside the direct medical sphere. We must realize how important social or cultural factors are in the results. The milieu in which we work has changed rapidly. There is a great increase in government involvement, great increase in educational attainment of the public and an evolution of "the wish to know." With the increase in knowledge of the public, the veil of mystique of the profession has been lifted and there is a realization of the limitations of the profession.

Medicine must understand that its relationship to the people needs more attention. The mark of failure of communication and education is already apparent, and this deficiency is reflected in the increase in legislation, regulation and litigation. Emphasis on cost-containment and cost-effectiveness will change the distribution of funds and change the structure of the profession.

Courts have begun to establish standards of care. Institutional review boards will take on real power to change the course of our activities. Academics have depended too much on the government for funds. We *should strengthen the relationship between industry and the profession. Avenues of interaction must be found and implemented.*

He anticipates, on the basis of basic and clinical research activities now in the pipe-line, that progress in the '80s will outstrip that of the past decades, especially in regard to the brain, behavioral sciences, genetics, and endocrinology. Advances in technology will continue at even a more fundamental level and impose changes in practice. "The 1980s is a time to soar with eagles, and this cannot be done if we bury our heads and act like turkeys."

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George S. Palmer, M.D., President, Federation of State Medical Boards.

> *"Bureaucracy cannot practice medicine; only individuals who have proper education and training can give this kind of service."*

Opening discussion on *Regulation of Medicine as a Dilemma of the Decade,* Dr. Palmer noted that regulation is an ominous and onerous word when it involves physicians. It usually means the intrusion of government and bureaucracy into the practice of medicine. Professions, almost by definition, should be self-regulatory. They are usually composed of high caliber persons, educated in a science or an art, who have ethics and codes of behavior. If the members do not adhere to these rules, they are usually disciplined. But some regulation is necessary in the public interest. This is demonstrated by the Boards of Medical Examiners, which were established in the interest of protecting the public, and traditionally run by professional members who know what the practice of medicine is all about. However, there has been a change in attitude stimulated by the news media, consumer advocates, the public, and legislators, based on the implication that the profession is not capable and cannot be trusted. They consider the Board of Examiners to be self-serving and incapable of disciplining fellow-physicians. This change in philosophy has been translated into statutes called the *Sunset Review Process,* by which Boards must undergo scrutiny. They must justify themselves, go out of existence, or be subjected to drastic results as seen in the Florida experience.

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Newton N. Minow, Esq., Senior Partner, Sidley and Austin, Chicago. As AMA Counsel he has dealt extensively with FTC litigation and appeals.

> *"Reasonable people may differ as to whether a regulation program is desirable but most agree on the desirability of programs which aim at upgrading the quality of care."*

In looking at the intrusion of the government into medicine thru regulations, Atty. Minow focused on *"Why are Regulatory Activities Happening?"*

Historically, the only need asked of physicians by Society as a whole was that it receive the best *quality* of care. The only obligation imposed on the *individual* doctor was to provide the highest *quality* of service capable by his or her expertise. It was assumed that Society would be best served if each individual doctor did the best he/she could to enhance the well-being of the individual patient. At that time the *individual* was paying the bill, and the welfare of the patient was more important than anything else. The heart of the code of self-regulation of the profession was then, just as it is now, that *the welfare of the individual patient was paramount.* Growing out of this concern were regulations designed to enhance the *quality* of care, such as self-regulation, state and Government licensing laws, or as in the case of Specialty Board Certification Programs, hospital Peer Review Committees, or by state and private regulations as in the case of continuing medical education requirements.

But it is possible that even such programs may be subject to abuse. Some regulations, adopted by the profession with most laudable objectives, can be used to cover purely selfish motives. For example, we all agree that the rule "Physicians should not solicit patients" is a very desirable rule promulgated to ensure high quality of care and that the patient not get into the hands of a deceptive practitioner. However, this rule should *not* be used to justify anticompetitive conduct.

During the last 15 years when quality care was paramount, change has occurred. *A new kind of regulation based on a different concern has developed.* This kind of regulation is based on the concern to control cost. This has been the outcome of changes in financing medical care. Now, most individuals are covered by either private or government insurance. Therefore, *the concern for the needs of Society,* particularly as perceived by the government, has *shifted to limiting and controlling the costs of care.* In earlier years, the physician was asked to consider only "what is in the best interest of my patient?" Now the physician must consider "what is best for my patient *and* what is it going to cost?" In 1980, Mr. Minow feels the pressure will be intensified as the direct result of the way change has occurred in the *method* of paying for service. The essential difference between the attitude of the private physician and the employee of the government is that the physician is concerned with the patient on a one-to-one basis while the government deals with thousands of doctors, millions of patients and billions of dollars. The government must deal with the problems *en masse.* That is where the clash occurs. The Federal Register is replacing the medical journals. Rules and regulations are becoming more and more dominant in all our lives.

Some examples of government intrusion are: (1) *Utilization Review Regulations* issued by HEW in 1975 which said that "Medical necessity for admission of Medicaid and Medicare patients be established within one working day after hospitalization." This told the physician that he or she would be second-guessed by government. This was appealed and the AMA won its battle in the courts. (2) *The Certificate of Need Law* which rules that an office or hospital cannot expand without government approval even if private money is involved. After a terrific battle, a cooperative approach was accomplished in the interest of the patient and the doctor. This form of cost-motivated regulation by government is increasing.

The *FTC has another attitude.* They say, "Regulations don't work, so let's put it all in the marketplace—open up competition, get rid of licensure and other restrictions—then costs will come down." They are challenging the role of the Profession in accrediting medical schools. They say doctors should not be allowed on Boards because of conflict of interest. This process, which they call "De-Regulation," only means more and more rules, not less! Lawyers are becoming busier than ever settling disputes!

People today are concerned about regulations from different perspectives. "Dr. Minow" would offer a solution to the dilemma: "Government should stop perceiving doctors as having bad motives and doctors should stop viewing government as having bad motives. They should start communicating with each other and looking at each other, not as partners, but as cooperative agents in attempting to do the best thing for the public." First, they should abandon the adversarial role. Second, the Profession should get a lot tougher in policing its own ranks if it is to establish credibility with the Public. Finally, get into issues on which you can take a collective stand. Be out in front and *lead the fight on issues* such as pollution, energy, and mental retardation.

******

Thomas Ferguson, M.D., President, Council on Medical Specialty Societies.

> *"As physicians began to limit their activities to specialties they* voluntarily *invoked regulations as a natural outgrowth to improve quality of the specialty."*

Speaking on *Regulation of Medicine by Segments of the Profession,"* Dr. Ferguson elaborated on the question "Can the Profession Regulate Itself" to which Dr. Palmer had answered: "Yes. There is no better demonstration than that of the Specialty Boards."

By definition, Dr. Ferguson said, "Regulate means to improve a condition by bringing order to it rather than to involve restrictive or punitive measures." As physicians began to limit their activities to specialties they *voluntarily* invoked regulations as a natural outgrowth of physicians' *attempt to improve* the *quality* of a specialty. The first Specialty Board, formed by Ophthalmologists in 1917, was followed by the American Board of General Surgery in 1936. After a proliferation of specialties, a coordinating body was established in 1933, later recognized as the American Board of Specialty Organizations. At present there are 276,015 Board-Certified Members representing more than one-half of the physician population in the U.S. Motivation for excellence is manifested by setting essential goals for safety of patients. Such regulation will not only continue but increase. 95% of Family Practice students indicate they will seek Board Certification.

Recertification is a clear example of what lies ahead although consensus of the meaning of certification has not been reached among the Boards. The question is: Will it be a medical degree *plus* a medical specialty-certification as an alternative to State licensure to allow unrestricted practice in a State? Or, will it be a *single* specialty diploma awarded only after completion of both medical school and graduate medical education as a required license to practice anywhere in the U.S.?

******

E. Harvey Estes, M.D., Chairman, Department of Community and Family Medicine, Duke University Medical Center, Durham, North Carolina.

> *"The Nurse Practitioner should function under the umbrella of the physician."*

Discussing the problems of *"Physician Extenders"* Dr. Estes noted that the PA concept emerged in the late 1960s as a new profession especially trained to carry out tasks which had been the exclusive province of the physician but who also could work under the supervision of a physician. The need for regulation was recognized. All advised that this profession *not* be licensed because the law requires specification of functions which would be very difficult to achieve. Alternatives are: (1) delegation-type statutes, or (2) regulatory type statutes. Most states adopted regulatory procedures. The National Board of Medical Examiners has an examination which allows individuals to use the term "Certified." They must be trained by the medical Profession and are authorized to practice under mandated supervision of the physician and under the license of the physician.

The regulation applying to Nurse Practitioners has been disjointed. It poses a major problem because the N.P. is also a member of an independently licensed Profession (i.e. Nursing). The organized Nursing Profession has insisted that it take its own course although it has not yet developed a standardized program. In some areas, such as Pediatrics, they have joined together and evolved an accreditation system. An impasse has been reached because nursing is an independent profession, and yet the N.P. must practice under supervision of a licensed physician, who is the supervisor of the activity of one to whom some responsibilities are delegated. The strain is increasing as nurses attempt to gain greater authority. These problems are placing a new load on Medical Examiners.

******

Further valuable statements were made by other representatives of academe, the legal profession, and Government regulatory agencies who participated in the Congress. Their review of the current status of medical education, with discussions of the strengths and weakness of the system, is of special interest and importance at a time when issues posed by the report of the Council on Medical Education are about to be considered by the AMA House of Delegates in December. Decisions made at that time may influence the course of medicine for many years to come.

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Hospital Budget Review: Is There a Better Way?

DONALD A. BERKOWITZ, C.P.A.

While few in the health care field in Connecticut would deny that mandatory state budget review for hospitals has had some impact on health care developments since it was initiated in 1973, few would agree with the claims by regulators that most, if not all, of this impact has been beneficial.

On the contrary, while some savings may have been realized as a result of cuts made during the course of the reviews, which take place every year from July 3rd to September 15, it is equally as true that the process itself, as carried out by the state Commission on Hospitals and Health Care (CHHC), hardly has been what one could call a model of efficiency or fairness. The mere fact that the 75-day review period often has involved round-the-clock meetings and hearings, plus the fact that since 1976 anywhere from one to 33 hospitals have had to appeal to the courts each year for relief, are in themselves testimony to the acrimonious atmosphere within which budget review takes place.

Is a fairer, more efficient process possible or is the current process the best one can hope for given the nature of regulatory affairs? To answer those questions, one need first understand how one particular aspect of the review process—the so-called Overall Reasonableness Test (ORT)—works.

The ORT is the first review a proposed hospital budget faces upon its submission to the CHHC each year on July 3rd. It consists of a series of tests which seek to determine whether the net revenue, price, expenses and volume increases which a hospital is proposing for the next fiscal year are, in fact, "reasonable" according to the CHHC's own definition of that word. This test is primarily based on what the CHHC believes the inflation rate for hospitals will be during the coming year. If a hospital's inflation estimate and that of the CHHC's coincide, the hospital's budget proposal more than likely will conform to the "ORT" test and be deemed "reasonable" with no further review.

Where problems have arisen, however, is that each year the CHHC's inflation predictions have been so low that it has been nearly impossible for most hospitals to accept them and still obtain a workable budget. This year, for example, using data it obtained from the February issue of a government finance magazine, the CHHC predicted that hospital inflation.

Fiscal 1981 would be 8.8 percent, despite more recent expert predictions that 10 percent is a more likely figure. As a result, this year, only eight of the 35 hospitals were able to pass the ORT and avoid further detailed and time-consuming review.

During the second half of the review process, however, it soon became apparent how unrealistic the 8.8 percent figure was, and the Commission was forced to informally revise upwards its inflation prediction for 25 of the 27 hospitals that did not pass the "ORT" test. As a result of that action, the CHHC now faces a situation where the original eight "ORT" hospitals and 2 others are asking that revisions be made in their cases as well.

It is CHA's contention that a great deal of the time spent this year debating and revising inflation predictions could be avoided if the Commission were willing to accept the predictions of an outside expert who also was acceptable to the hospitals. Acceptance of such predictions would not only increase the number of hospitals not having to go through the second-stage more-expensive review, it would also free up Commission time so that it could concentrate on those hospitals whose budget requests required the detailed scrutiny for which the second stage was designed.

By the CHHC's own admission, the current budget review process is a "tortuous" one, both for it and the hospitals. It is the hospitals' belief, however, that the process need not be so difficult for so many hospitals if only the Commission would approach it with a greater degree of flexibility and reasonableness than it has in the past.

DONALD A. BERKOWITZ, Connecticut Hospital Association's Vice President, Finance, Wallingford, CT.

Donald A. Berkowitz is the vice president for finance with the Connecticut Hospital Association. He received his B.A. from the University of Michigan and CPA certificate from New York State. Prior to joining CHA in 1972, he was chief financial officer at the Griffin Hospital in Derby for 16 years.

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Current Medicolegal Issues

THE CITATION

Indictment Against Eight MDs for Alleged Antitrust Violations Dismissed by New York County Court

An indictment charging eight physicians and an organization they formed with criminal violations of the state antitrust law by refusing to treat no-fault automobile insurance accident victims and workmen's compensation patients was dismissed by the County Court for Nassau County, New York.

According to the court, the physicians had organized a group, the Surgical Specialties Association of New York, Inc., to protest the fee schedule adopted as part of the state's no-fault automobile insurance law, and to protest administrative abuses in the compensation system. The no-fault law required that physicians who treat persons injured in automobile accidents be compensated at a maximum rate equivalent to the minimum fee schedule adopted by the state workmen's compensation board.

Initially, the physicians' group attempted legislative reform. As these efforts failed, the court noted, they agreed among themselves to resign their authorizations to treat work-related or automobile accident injuries. Thus, the court concluded, over 250 physicians in the Long Island area became unavailable to nonemergency patients with such injuries.

The eight physicians defended themselves by contending that the medical profession is exempt from the provisions of the Donnelly Act, New York's antitrust law. The Attorney General, who obtained the indictment, argued that U.S. Supreme Court decisions with respect to federal antitrust laws should guide the application of the state law. The physicians' alleged concerted refusal to deal would subject the physicians to the provisions of the federal antitrust law known as the Sherman Act, the court acknowledged.

The court noted that New York's highest court had determined that the Donnelly Act does not apply to the legal profession. Since there is no valid distinction between the legal and the medical professions with respect to the Donnelly Act, physicians as well as attorneys are exempt from its provisions, the county court concluded.

"In this Court's view, the conduct of the physicians, the concerted refusal to deal, is in the nature of a boycott, and reprehensible notwithstanding what may be valid complaints . . .

"The concerted refusal to treat the injured and the maimed prevents those innocent victims from receiving medical care from the only ones qualified by training and education to render such care. There are no 'do it yourself kits' for those requiring orthopedic, plastic or neurological treatment. The social harm inflicted is immeasurable and outweighs any individual inequities. The public is made to suffer in what is essentially an economic battle—a fight over money, which is inconsistent with the physician's oath to humanity," the court said.

The court granted the physicians' motion to dismiss the indictment on the ground that the medical profession is exempt from the Donnelly Act. Further, the court suggested that the Legislature address the situation complained of by the physicians.—*People of the State of New York v. Roth* (N.Y.Co.Ct., Nassau Co., Indictment No. 48184, Aug. 10, 1979)

Editor's Note: The above case confirms that criminal indictments can be brought against physicians by the U.S. Department of Justice and State Attorneys General for violations of state and federal antitrust laws. The U.S. Department of Justice has been successful in obtaining criminal indictments and prison sentences for "white collar" corporate executives in several antitrust cases during the past two years.

Since there is no exemption for the "learned professions" from the Sherman Antitrust Act and many of the state antitrust laws, it is unlawful for physicians to engage in boycotts and concerted refusals to deal.

Physicians have lawful means to accomplish redress of their grievances. They can petition their legislatures and they can seek redress in the courts. To take collective action that results in harm to the interests of patients only increases the possibility that their associations will be subjected to investigation, criminal indictments will be brought under state and federal antitrust laws, and existing exemptions from the application of state antitrust laws will be eliminated by state legislatures.

MD May Refuse to Give Deposition in His Office

A court reporter had no cause of action against a physician for the physician's refusal to give a deposition in his own office in the presence of the court reporter, a Washington appellate court ruled.

The physician had treated the reporter's father-in-law for a job-related back injury in January 1974.

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During the course of hospitalization the reporter and the physician exchanged angry words. On three later occasions, in September 1974, April 1976 and January 1977, the physician had refused to give depositions in the presence of the reporter. The reporter had been hired by a different attorney on each occasion to record the physician's deposition in the physician's own office. Each time the physician refused to give his deposition because the reporter was present.

In March 1977, the reporter filed suit charging tortious interference with his business relationships. The physician responded with the defense that he had the right to refuse entrance to anyone to his private property, including his medical office. The trial court agreed and the reporter appealed.

Affirming the decision, the court said that the physician had an absolute privilege to interfere with the business transactions of another person on the physician's own property. The reporter argued that the physician was not exercising that right when he refused to testify. The court said that the physician did not have to specifically state that he was exercising his privilege to exclude persons from his property.—*Ciccarello v. Gottlieb,* 592 P.2d 679 (Wash.Ct. of App., March 15, 1979)

$35,000 Awarded to Patient Who Fell from Tilt Table

A hospital was liable for injuries suffered by a patient when he collapsed during physical therapy and dislocated his recently rebuilt hip, an Oregon appellate court ruled.

In December 1975, when the patient was 75 years old, he underwent a total hip replacement. On the sixth day after surgery the patient began a program of physical therapy. He was placed on a tilt table and twice elevated to a standing position for ten-minute periods. He tolerated that therapy without incident. On the next day he was again elevated to a standing position and instructed to walk between two parallel bars. He walked six lengths, about 60 feet, and then walked back to the tilt table. When he reached the table, he collapsed and dislocated his recently rebuilt hip. He had to undergo a manual surgical procedure to relocate his hip.

In a malpractice suit against the hospital, the patient claimed negligence in letting him fall from the table. A jury awarded the patient $35,000, and the hospital appealed.

Affirming the decision, the appellate court said that testimony by an expert witness was properly admitted. The expert testified that by letting the patient walk 60 feet on his first walk after surgery the physical therapist was taking a chance of overfatigue. The testimony was not used to establish excess walking as a separate theory of negligence but to establish the circumstances around the incident. The court also said that the testimony by the physical therapist about his actions when the patient complained about feeling weak and faint established negligence. He stated that he did not call for help or strap the patient or support him when he complained about feeling weak, the court noted.

The judgment was affirmed.—*Forsyth v. Sisters of Charity of Providence,* 593 P.2d 1270 (Ore.Ct. of App., April 23, 1979)

Physician's Malpractice Insurance Policy Cancelled Because of Concealment of Facts

A malpractice insurance policy was null and void because the physician to whom it was issued misrepresented and concealed that he had moved from Alabama to Louisiana and had licensing problems with the state, a federal appellate court in Louisiana ruled.

The physician obtained malpractice insurance in 1972, while he was practicing in Alabama. The policy was renewed in 1973. Later, the physician moved to Louisiana, where he was issued a temporary permit, which expired in June 1974 and could not be renewed. The Louisiana State Board of Medical Examiners then twice rejected his application for a permanent permit. A Louisiana court ruled that the physician had no legal right to practice medicine after his temporary permit expired.

In June 1974, the physician, by then a Louisiana resident, requested renewal of his malpractice policy on stationery bearing his former Alabama address. The policy was renewed, and the policy and premium were mailed to him at the Alabama address. The policy listed his office address in Alabama and stated that he was registered and licensed to practice in Alabama. At no time did he inform the insurance company of his move to Louisiana or of his license problems in that state.

The insurance company learned of those facts when it was informed of a malpractice suit against him. The company then cancelled the policy and returned the premium to the physician. The company also filed suit to declare the policy null and void because of the misrepresentation and omissions made by the physician. A trial court granted summary judgment for the insurance company, and the physician appealed.

Affirming the decision, the federal appellate court said that the policy was null and void. Both the policy underwriter and the agent stated that the policy would not have been renewed if the true circumstances had been known. Because the policy was renewed on the strength of the physician's misrepresentations, it was void, the court said.—*Aetna Casualty & Surety Company v. Evers,* 590 F.2d 600 (C.A.5, La., Feb. 28, 1979)

The President's Page

In the next month the Connecticut State Medical Society will begin collecting information concerning its committees. A large portion of the Society's work is carried on through its very important committees. Nominations will be made, members and chairmen then being elected by the House of Delegates. The House elects the committees, sets the rules and policies which govern their operation, initiates programs, assigns projects and provides budget and staff necessary for their operation. Committee activities vary from preparation of reports and studies to liaison with State agencies, to peer review, to scientific studies. Under rules recently adopted, the chairmanship of each committee must rotate every three years and committee members who do not participate are to be replaced.

As in all organizations, some committees are very productive and others not so active. Presently the Committee on Professional Liability is both very active and effective. It is negotiating premiums and agreements with Aetna, developing the Patient Injury Prevention Program, working with a consulting firm in developing plans for a captive insurance company, and also on a legislative program. With the help of an experienced staff and able legislative representation and often in cooperation with other associations, the Legislative Committee can point with pride to its legislative record. No anti-physician laws have passed the legislature in the past three years and many constructive measures have become law. The Committee for Liaison with the State Department of Social Services has developed considerable status with the Department and has been influential in making fee schedules as reasonable as possible and in minimizing the amount of red tape necessary in the care of State patients. The Statewide Medical Planning Committee has chaperoned the 46 chapters of the A.M.A. commissioned "Study on the Cost of Medical Care" through the various committees, along with supervising the ambulatory care study, and is presently developing information on health planning in industry, labor, the health insurance industry, etc.. The Committee on Emergency Medical Care has been playing a major role in the developing emergency medical system in the State. Many other committees are equally active and also contributing to the effectiveness of the profession and the welfare of the patient.

The structure of the Society is such that it diffuses responsibility and provides for participation by many physicians. Any member may attend committee meetings as well as House of Delegate and Council meetings. Members may participate in Society activities by introducing resolutions in the House of Delegates, either as individuals or through county societies or the medical sections. Matters may also be brought to the appropriate committees for study and advancement through the organization. Members can be more effective, however, by serving as delegates to the House or as members of committees.

Connecticut Medicine will publish in this issue a "Committee Service Questionnaire" including a list of the Societies Committees. Those who feel they have something to offer and are sufficiently interested to participate regularly should notify the State Society or the County Society of their interest and qualifications. The Councilors and County Society officers should soon know of vacancies on committees and will nominate candidates for these positions. Nominations are made in the Committee on Preliminary Nominations, consisting of the eight councilors and chaired by the president.

Too often the list of available, qualified nominees is not adequate and the Committee must solicit candidates to assume these important responsibilities.

W. Raymond James, M.D.
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Reflections from the Dean's Office

The New Biology and the Old Art

ROBERT U. MASSEY, M.D.

The new biology was the theme of the fall meeting of the Association of American Medical Colleges; the assembled deans and faculty members considered how this new learning should affect medical education and medical practice in these last two decades of the century.

It may have been the pre-Socratic philosopher Democritus who started us on the road to the new biology. He taught that everything in the universe consisted only of atoms, and that the size, shape, and qualities of any piece of matter, animate or inanimate, could be explained by the way atoms of different sizes, shapes, and weights were combined or entangled. Democritus did not imagine atomic nuclei surrounded by electron shells, nor did he picture, as we have come to do, the curled and twisted large molecules which by their shapes and charges determine the nature of all living things. But he and the others of the early Greek philosophers did pretty well: they had a notion that if we knew enough we could explain all phenomena naturally, without invoking either demons or gods.

In the 2500 years which have followed Democritus, biology lagged behind chemistry and physics in reaching that goal of mechanistic explanation; during most of those centuries the practice of medicine lagged even further behind biology. More than a century after Harvey demonstrated by quantitative methods that the blood must circulate, students in Edinburgh, the best medical school in Europe in the mid-18th century, were taught that disease resulted from the imbalance of the four humors. Bleeding and purging, practices which rested upon the humoral theory, lasted in some places until a generation or two ago.

Modern biology may have begun in the 6th century B.C. on the coast of Asia Minor, or it may have begun with Harvey, or with Virchow, Pasteur, or Koch. Vitalism disappeared sometime in the 19th century, and while it may yet have some secret adherents, no one seriously holds that progress in biology can be made by appeal to any non-material principles.

Cellular and molecular biology provides a powerful means for understanding genetics, immunology, and the functioning of the nervous system. Reductionism has not turned out, as some predicted, to be just a new kind of scholasticism; reductionist explanations are necessary to understand how larger systems work, and biologists can now do more than describe nature.

The gaps between physics and biology, and between biology and medicine, have been narrowing faster with each decade. Much of medicine in twenty years will be incomprehensible without understanding the new biology. The science of 1900 provided sufficient intellectual ground for medical practice in the early years of this century; it will no longer do for today nor for the new century twenty years away.

This does not mean that medicine is to be replaced by science, nor that the new biology will replace the old art. Molecular biology does not explain everything about us, nor about our works. As physics and chemistry explain more, we come to understand more clearly what it is they do not explain. We suspect that the new neurobiology may not explain consciousness nor personality, but it may explain memory and learning; it will tell us a great deal more about consciousness than we now know, but it will leave some essential things unexplained; that will only help us to sharpen our definitions and to ask better questions. We do not have many more answers than Tennyson had when he contemplated the flower in the crannied wall.

I am not sneaking in with a new vitalism, but rather suggesting that the new science may have helped to start up a renaissance in humanism. What it means to be human will not be found entirely in the shape of large molecules, but then neither will it be understood without knowing about cell membranes and neurotransmitters. Because the biological sciences have now taken their position among the hard sciences, the humanities may return with safety to the field. There is, to be sure, still some confusion about who owns what in the behavioral sciences, and the humanists and behaviorists may have a difficult time with one another for awhile. The biologists and philosophers seem to have sorted it out; they have sensed that it is the questions, not the answers, which matter.

In medical education, the new biology, which is the latest flowering of the old Renaissance, and the humanities, which are experiencing a kind of second rebirth, have come together to produce a reformation of the curriculum as fundamental as Flexner's. If we look beyond our noses, we might discern something very like that happening in all of education.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Medical Decisions for Incompetent Adults: The *Spring* Case I

JOSEPH M. HEALEY, J.D.

During the past five years, several highly publicized legal cases addressing problems in medical decision making for incompetent patients have provided a context for several states to explore the values, principles and policies involved in such cases. The Quinlan case[1] is, perhaps, the most famous of these cases. Among the states, Massachusetts has clearly been a leader in judicial decisions in cases of this type. Recently, the Massachusetts Supreme Judicial Court reveiwed the tragic case of Earle Spring[2] and provided a comprehensive review of Massachusetts' attempt to provide guidelines to patients and providers concerning their respective rights and duties. As we in Connecticut continue to grapple with similar cases without the benefit of clear legislative or judicial guidelines, the experience of our neighbors to the Northeast will continue to provide an opportunity for thoughtful reflection and discussion.

Earle Spring had been born in 1901. He had been married for more than fifty-five years and lived with his wife near his only child, an adult son. Mr. Spring had been the chief chemist and metallurgist at a local tool and die plant. He retired in 1966 and was spending his retirement doing the things he enjoyed—hunting, fishing and traveling. In November, 1977, he experienced a series of medical problems which culminated in pneumonia and kidney failure. He survived this crisis and began dialysis treatment on an outpatient basis. His physical condition stabilized but his mental condition seriously deteriorated. At times, he was belligerent and disruptive. He was increasingly unable to take care of himself. In October, 1978, his wife suffered a stroke and was placed in a local nursing home. One month later, Mr. Spring was placed in the same nursing home. Dialysis was continued on an outpatient basis. Ms. Spring recovered sufficiently to permit a discharge to her home where she continued her recovery. Mr. Spring's condition continued to deteriorate. His mental confusion seemed total and his conversation seemed unintelligible. His disruptive behavior necessitated the use of heavy sedation. Ms. Spring and her son sought to have dialysis discontinued, although such a discontinuation would result in his death. They petitioned the County Probate Court for an order to that effect. The Court granted their request, ordering the temporary guardian to refrain from authorizing any further life-prolonging medical treatment. Several appeals followed, leading to the Supreme Judicial Court's consideration of the case.

The Massachusetts Supreme Court set forth the basic principles involved in cases like those of Mr. Spring.

> "A person has a strong interest in being free from nonconsensual invasion of his bodily integrity, and a constitutional right of privacy that may be asserted to prevent unwanted infringements of bodily integrity. Thus a competent person has a general right to refuse medical treatment in appropriate circumstances, to be determined by balancing the individual interest against countervailing State interests, particularly the State interest in the preservation of life. In striking that balance, account is to be taken of the prognosis and of the magnitude of the proposed invasion. The same right is also extended to an incompetent person, to be exercised through a "substituted judgment" on his behalf. The decision should be that which would be made by the incompetent person, if he were competent, taking into account his actual interests and preferences and also his present and future incompetency."[3]

Of great concern to Massachusetts health care providers under prior cases, had been confusion about the extent to which prior judicial approval was required before life-prolonging treatment could be withheld from an incompetent person.

Next month, we will continue our review of the Spring case, focussing on this issue of prior judicial approval and on the nature of a decision not to treat.

REFERENCES

1. *In re Quinlan,* 70 N.J. 10 (1976)
2. *In the Matter of Earle N. Spring,* 405 N.E. 2d 115 (1980)
3. *Ibid.,* p. 119

JOSEPH M. HEALEY, J.D., Assistant Professor of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

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EDITORIALS

The Surgical P.A.—A Community Hospital Resource

For thirty years I have practiced as a general surgeon on the staff of the Norwalk Hospital. During most of that time I have been intimately involved in the design and implementation of our surgical residency program. From this vantage point I was able to evaluate the particular strengths and limitations inherent in that training process.

Five years ago, the Norwalk Hospital lost its approval for a free-standing four-year surgical residency. To meet the educational and service needs of the Department of Surgery, a P.A. surgical residency program was created through the joint efforts of the Departments of Surgery of Norwalk Hospital and Yale University School of Medicine. This program, supported from its inception by William F. Hughes, M.D., former Chairman, Department of Surgery, Norwalk Hospital, and Arthur Baue, M.D., Donald Guthrie Professor of Surgery and Chief, Department of Surgery, Yale University School of Medicine, is described elsewhere in this issue.

From its inception, I have been an interested participant in this innovative effort. After five years I feel confident that the utilization of trained surgical P.A.s can adequately fulfill the housestaff needs of a modern community hospital.

At the Norwalk Hospital these needs are met by employing eleven full-time staff surgical P.A.s, all of whom have completed the residency training program, and ten P.A. surgical residents. Functioning under the supervision of the attending surgeon, the P.A. participates in all aspects of pre-, intra-, and postoperative care of the surgical patient and staffs the surgical side of the ICU. The trained surgical P.A. has demonstrated excellent manual skills, and, more importantly, has developed sound surgical judgment. Their efforts are actively supported by administration, the surgical attending staff, the Department of Nursing, and the attending staffs of the other clinical departments.

This is not to say that the surgical P.A. and the surgical resident are interchangeable, because indeed they are not. Differences do exist and must be identified.

For example, a surgical resident rotates from service to service at relatively frequent intervals. This is designed to give him or her an exposure to a variety of techniques, attitudes, and disciplines. The P.A. on the other hand may well remain on a given service for several years. For the surgical team this provides a continuity not previously experienced.

Whereas the surgical resident trains to develop the skills necessary to become an independent operating surgeon, the surgical P.A. is trained to develop skills and judgment as a surgeon's assistant, a qualified team member.

The surgical resident has had extensive training in basic sciences which few P.A.s have experienced. However, I have observed that the surgical P.A. very often has a greater sensitivity to the concerns and emotional needs of the surgical patient.

It is a mistake to try to utilize the surgical P.A. as an alternative housestaff member unless we candidly acknowledge their particular needs.

For example, we cannot expect a group of highly trained dedicated health professionals to work a hundred-hour week for years on end. The sooner the schedule approximates a forty-hour workweek the higher will be the morale and productivity of the participants.

One of the major frustrations experienced by the surgical P.A. is a limitation of upward mobility which is often combined with economic constraint. This will be a continuing challenge for those institutions which are increasingly utilizing this emerging medical resource, and must be addressed in a creative manner.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Any evolving program has its attendant problems. Nevertheless, because of the demonstrated ability of the trained P.A. to improve the quality of medical care, the evidence strongly supports their increased utilization in the community hospital setting. Each institution must structure a program that will best satisfy its requirements. In my judgment, it can best do so by remaining sensitive to the intellectual, social, and economic needs of the P.A.

Malcolm S. Beinfield, M.D., FACS

Senior Attending Surgeon, Norwalk Hospital
Director, Norwalk Hospital/Yale
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Letters to the Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed by all authors, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.

DRINKING, DRIVING AND IMPLIED CONSENT

To the Editor: Connecticut has the 3rd worst record for drunken driving convictions of the 50 states. Much of the problem lies with its unworkable "implied consent" law.

The law exacts, for all practical purposes, no penalty for refusal to submit to a chemical test for alcohol intoxication. Since conviction for drunken driving is almost impossible without such a test, most suspects refuse to be tested and thus escape prosecution on that charge.

Thirty-nine states have strong "implied consent" provisions in their laws. Connecticut did pass a new Driving While Intoxicated statute this past year, P.A. 80-438, but it is only marginally better than the old law.

The law enforcement agencies and the various providers of alcoholism services within the State have joined forces in a campaign for stronger legislation in 1981 which would make the penalty for refusal to submit to alcohol testing the automatic loss of driver's license. Enactment of such a law would aid police in getting drunken drivers off the road, thus reducing the immense human and economic toll which they impose upon society.

I urge all physicians to help with this effort by exerting their influence on all segments of the State government with special attention directed toward the Judiciary Committee whose Chairman, Representative Richard Tulisano, has been a main opponent of meaningful change in this area.

G.L. Springer, M.D.

Chief, Department of Emergency Services
The William W. Backus Hospital
Norwich, CT

On Terminating the Physician-Patient Relationship

From time to time physicians inquire as to the conditions under which it is ethical to request a patient to seek medical care elsewhere.

Among the situations which may justify the discharge of a patient are:

1. *Abusive treatment* of the physician by the patient.
2. Continued *refusal to pay bills* when the physician has used all reasonable means to collect the fees and is satisfied that the patient is financially able to pay.
3. When the disease from which the patient suffers is *foreign to the physician's expertise.* In this situation, names of other physicians should be suggested to the patient.
4. Repeated *failure to follow* the physician's advice and treatment.
5. *Excessive consultations with other physicians* without the knowledge and consent of the primary physician, after making certain that the patient understands the hazards in such situations.
6. *Incompatability of personalities* which interferes with the proper investigation and treatment of the patient's illness.
7. When a physician desires to *limit his or her practice.*
8. When a physician *retires,* a courtesy letter may be sent to each current patient indicating the date of retirement, suggesting names of other physicians in the area, and indicating where the record may be obtained by the subsequent physician, or a suitable notice may be published in the newspaper.

The Board of Registration in Medicine has mandated that physicians must treat Medicaid patients in the same manner as other patients are treated in similar circumstances who are not recipients of public assistance.

Massachusetts state law has mandated that physicians cannot refuse to give credit to any patient because the patient is on public support. (Acts 1971. Chapter 726. Amends GL c. 151B. Section 4.)

A patient should never be abandoned. Adequate time must always be allowed for the patient to find another physician before services are terminated. Records must be made available to the new physician. The names of one or more physicians in the area capable of treating the patient's condition should be furnished if the patient requests them. The patient must always be seen in an emergency.

For the Committee on Ethics and Discipline
John W. Norcross, M.D., *Chairman*
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Urban H. Eversole, M.D.
Lamar Soutter, M.D.
Bernard Tolnick, M.D.

—*Massachusetts Medical Society Newsletter, Vol. XIX, No. 10, Dec. 1979*

Cardiology: July '81. Age 29. Nat'l. bds., cert. MD: Univ. of Baroda, Kenya. Int.: St. Joseph's Infirmary, KY. Res. and fellowship: Univ. of Louisville affil. hosp. Like to limit practice to Card. Trained in Cardiac Catheterization, 2D and M mode Echo-cardiography, Nuclear Card. (Thallium and Blood Pool imaging), Exercise testing, Holter monitoring. Will consider all types of practice except industrial in large or med. community. Contact CSMS/IM/Card.-A.D.

Nephrology: Available now. Age 37. FLEX. AB-elig. MD: Univ. of Rome, Italy. Int.: Cabrini Health Ctr. Res.: NY Infirmary Hosp. Fellowship: Long Island Coll. Hosp., Jersey Shore Med. Ctr. Would consider doing IM only, but would prefer doing at least some Nephrology. Solo, grp. or assoc. practice in large or med. community. Richard Eanni, M.D., 19 Fernandex Dr., New Windsor, NY 12550.

Gastroenterology: July '81. Age 28. Nat'l. bds., cert. MD: Tufts. Int. and res.: Baystate Med. Ctr., Mass. Fellowship: Einstein. Grp., assoc. or institutional practice. Would like to be affil. with teaching hospital. Paul S. Farkas, M.D., 1935-24 E., Eastchester Rd., Bronx, NY 10461.

Feb. '81. Age 37. Conn. license. Nat'l. bds., cert. Presently in practice. MD. Columbia P&S. Int. and res.: Roosevelt Hosp., NY. Solo practice in med. or sm. community in CT desired. Contact CSMS/IM-WF.

Rheumatology: July '81. Age 30. Nat'l. bds., AB-IM-cert. MD: Univ. of Wisconsin. Int. & res.: Memorial Hosp., Mass. Fellowship: Univ. of North Carolina. Will consider all types of practice except industrial in large or med. community. Michael A. Friedman, M.D., 135Loblolly Lane, Chapel Hill, NC 27514.

Rheumatology: July '81. Age 30. Nat'l. bds., cert. MD: NY Univ. Int. and res.: Boston City Hosp. Fellowship: Brown Univ. Program-Roger Williams Gen. Hosp. Would be interested in eventually building up primarily Rheu. practice but willing to start with Gen. IM Grp. or assoc. practice. John Guttell, M.D., 27 Putnam Rd., Foxboro, MA 02035.

July '81. Age 29. Nat'l. bds., elig.-6/81. MD: PA State Univ. at Hershey Med. Ctr. Int. and res.: Geisinger Med. Ctr., PA. Grp. practice desired in med. community in CT. Contact CSMS/IM-JRK.

Pulmonary: July '81. Age 33. AB-cert. MD: India. Int. United Hospitals, NJ. Fellowship: VA Hosp., Brooklyn. Also did res.: in otorhinolaryngology in India. Will consider all types of practice in CT. Brijinder S. Kochhar, M.D., 8501 Fort Hamilton Parkway, #2A, Brooklyn, NY 11209.

Rheumatology: Sept. '80. Age 31. Conn. license. Nat'l. bds., cert.-IM; elig.-Rheu. MD: NYU. Int.: Metro. Hosp.-Flower & Fifth Hosp. Res.: UConn affil. hospitals. fellowship: Robert B. Brigham Hosp. Will consider all types of practice. Would like to be involved with an active community hosp. which presently has housestaff program/or med. students. teaching responsibilities desired. Contact CSMS/IM-Rheu.-WL.

Oncology: July '81. Age 29. AB-cert. MD: India. Int.: India and Detroit Macomb Hosp. Res.: Jamaica Hosp., NY. Fellowship: Roswell Park Mem., NY. Solo, grp. or assoc. practice in med. community. Dattatraya S. Prajapati, M.D., 88 Slate Creek Dr., Apt. #5, Cheektowaga, NY 14227.

July '81. Age 33. AB-elig. MD: Guadalajara. Int. and res.: College of Medicine and Dentistry of NJ. Grp. or assoc. practice in med. or sm. community in CT. Tim Whiting, M.D., 9 Beaumont Place, Irvington, NJ 07111.

OBSTETRICS AND GYNECOLOGY

July '81. Age 29. Nat'l. bds., elig. MD: Temple. Int. and res.: Reading Hosp. and Med. Ctr., PA. Interested in joining a sm. grp. ideally with two other physicians in med. community. John C. Hughes, M.D., 417 Oak Terr., West Reading, PA 19611.

June '81. Age 33. AB-elig. MD: Univ. of Bologna. Int.: St. Joseph's Hosp., NY. Res.: SUNY-Buffalo. Grp. practice desired in large or med. community. Vincent Molinari, M.D., 144 Dellwood Rd., Amherst, NY 14226.

July '81. Age 28. Nat'l. bds., elig. MD: Boston Univ. Int. and res.: Univ. of Rochester affil. hosp.-Strong Mem. Hosp.; Highland and Genesee Hospitals. Grp. or assoc. practice in med. or sm. community. Native of New London, CT. Robert M. Spitz, M.D., 195 Hillendale St., Rochester, NY 14619.

ORTHOPEDICS

July '81. Age 39. MD: Italy. Int. and res.: United Kingdom. Also res.: Catholic Med. Ctr., NY. Grp. or assoc. practice in med. community. Contact CSMS/Orth.-JF.

July '81. Age 30. Nat'l. bds., elig. MD: Vanderbilt. Int. and res.: Montefiore. Solo or assoc. practice in CT. desired. Mark M. Kramer, M.D., 3450-12 Wayne Ave., Bronx, NY 10467.

PEDIATRICS

Ped. and Ped. Cardiology: Available now. Age 31. AB-cert. MD: Seth Med. Coll., India. Int.: K.E.M. Hosp., India. Res.: Kings County Hosp., NY. Fellowship: UCLA. Grp. institutional or HMO in CT. Parameswaran S. Aiylam, M.D., 3520 Keystone Ave., #3, Los Angeles, CA 90034.

Available anytime. Age 45. Conn. license. AB-elig. MD: London Univ., England. Will consider all types of practice except solo in med. or sm. community. Been in practice overseas, went back for more training in Gen. Ped. Contact CSMS/Ped.-ZSAM.

Ped. & Neonatology: July '81. Age 30. Nat'l. bds. Presently in practice. MD: India. Int.: Cook County Hosp., Ill. Grp., assoc. or institutional in large or med. community. Mangala V. Betkerur, M.D., 10015 S. Hill Terr., 28/202, Palos Hill, ILL 60465.

Jan. '81. Age 28. FLEX. AB-elig. Presently in practice. MD: India. Int. and fellowship: Metropolitan Hosp., NY. Res.: Kings County Hosp., NY. Solo practice desired. Kaushik J. Pandya, M.D., 30-49 70th Street, Jackson Hts., NY 11370.

SURGERY

Gen. and Vascular. Feb. '81. Age 31. FLEX. AB-elig. MD: India. Int. and res.: St. Elizabeth's Hosp., MA.-Tufts Univ. Sch. of Med., affil. hospital. Will consider solo, grp. or assoc. practice. S.G. Sankar, M.D., 36 Second Island Rd., Webster, Mass. 01570.

UROLOGY

June '81. Age 30. Nat'l. bds., elig. MD: Cornell. Int. and res.: NY Hospital. Solo, grp. or assoc. practice in CT. desired. Paul A. Church, M.D., 435 East 70th St., New York, NY 10021.

July '81. Age 31. Nat'l. bds., elig.-Urol. MD, int. and res.: NY Univ. Med. Ctr. Urol. res. rotation: Univ. Hosp., Bellevue Hosp., Manhattan VA Hosp., Mem. Sloan Kettering Hosp. for Cancer and Allied Diseases, Cabrini Health Care Ctr., all in NY. Solo, grp. or assoc. practice desired. Jeffrey Glasser, M.D., 166 E. 34th St., Apr. 19J, New York, NY 10016.

July '81. Age 35. FLEX. MD and int.: Univ. of Jabalput, India. Res.: Beth Israel Med. Ctr., NY, (surg. & urol.). Trained in microscopic surgery. Solo, grp. or assoc. type practice desired in med. or sm. community. Surapaneni P.R. Rao, M.D., 350 E. 17th St., #17E, New York, NY 10003.

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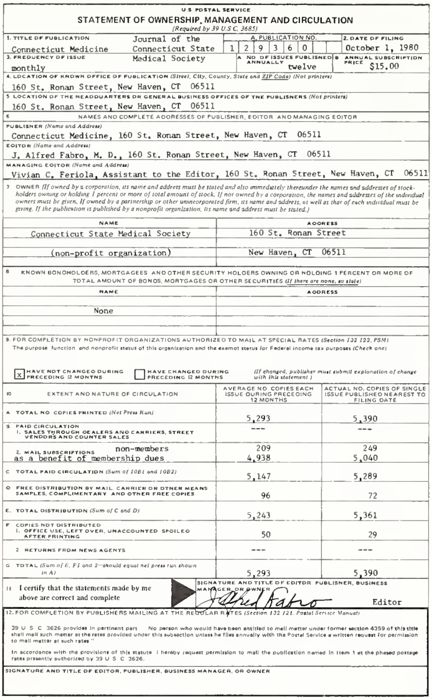

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A character all its own.

Valium (diazepam/Roche) is a benzodiazepine with a character all its own. Pharmacologically, it is a potent skeletal muscle relaxant and anticonvulsant (in adjunctive use), as well as an antianxiety agent. Pharmacokinetically, only Valium provides active *diazepam* as well as the active metabolites 3-hydroxydiazepam, desmethyldiazepam and oxazepam.

But the individual character of Valium is even more apparent clinically than pharmacokinetically. And far more significant. That's because of the patient response obtained with Valium. A response which brings a calmer frame of mind. A response which has a pronounced effect on the somatic symptoms of anxiety, particularly muscular tension. A response which helps the patient feel more like himself again because of the way Valium reduces the overwhelming symptoms of anxiety and psychic tension.

Another important aspect of the clinical character of Valium is safety. Though drowsiness, ataxia and fatigue are possible, these and more serious side effects are rarely a problem. Of course, as with all CNS-acting drugs, patients taking Valium should be cautioned against driving, operating dangerous machinery or the simultaneous ingestion of alcohol.

Unquestionably, many psychotherapeutic agents, including other benzodiazepines, have antianxiety effects. But one fact remains: you get a certain kind of patient response with Valium. It's a response you want. A response you know. A response you trust as part of your overall management of anxiety and psychic tension.

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Before prescribing, please consult complete product information, a summary of which follows:

Indications: Tension and anxiety states; somatic complaints which are concomitants of emotional factors; psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy).

The effectiveness of Valium (diazepam/Roche) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Contraindicated: Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms (similar to those with barbiturates and alcohol) have occurred following abrupt discontinuance (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

> ***Usage in Pregnancy:*** **Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other antidepressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. *Adults:* Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. *Geriatric or debilitated patients:* 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) *Children:* 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

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Ultrasound in the Evaluation of Renal Masses

ARTHUR T. ROSENFIELD, M.D., ROBERT K. ZEMAN, M.D.,
JOHN J. CRONAN, M.D. AND CHESTER J. KAY, M.D.

Each year approximately 600,000 new renal cysts appear in adults in the United States.[1] The clinician, therefore, constantly faces the problem of evaluating asymptomatic renal masses which have been noted incidentally on the excretory urogram (IVP). Ultrasound is a rapid, safe, accurate and non-invasive method of evaluating renal masses; during the past five years improvements in ultrasound instrumentation and technique have greatly enhanced its value in the evaluation of the kidney.[2] [3] [4] This paper defines the role of ultrasound in the evaluation of renal masses and presents an approach to renal masses utilizing modern ultrasound.

General Approach

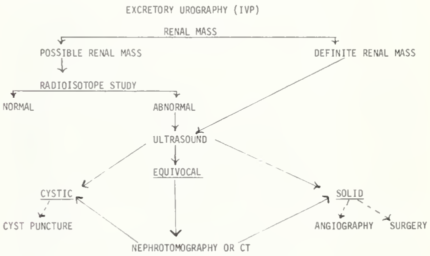
Identifying a Renal Mass

Almost invariably, renal masses are identified initially on the excretory urogram, although occasionally they present simply as a palpable abdominal mass. If a definite mass is identified on the excretory urogram, ultrasound should be performed. If there is a question as to whether an apparent lesion is a renal mass or normal tissue simulating a renal mass, a radioisotope study of the kidney is generally considered the best test. Normal findings require no further action; but abnormal results should be followed by ultrasound study. An outline of our approach to renal masses is presented in Table 1.

Radioisotope Study—For evaluating the renal parenchyma, the isotope Tc99m glucoheptinate provides the optimal combination of accuracy and low radiation dose to the patient.[5] Delayed scans of the kidney demonstrate activity within the cortex but not within the collecting system. Lesions of at least two and one half centimeters will appear as a zone of decreased activity within the renal parenchyma, while normal tissue, including "pseudotumors" will have normal or increased activity

Table 1

EVALUATION OF RENAL MASSES



Ultrasound—Ultrasound plays a major role in the differentiation between cystic and solid structures by evaluating the acoustic properties of the mass. If the mass is cystic and the patient is a surgical candidate, cyst puncture is indicated. If the mass is solid, either surgery or angiography to evaluate the vascular supply of the lesion should follow.

In the few cases in which an optimal ultrasound scan is not obtained, computerized tomography should be used to evaluate the kidney in a similar manner. If CT is unavailable, formal nephrotomography should be performed following the injection of a bolus of contrast medium or during an infusion of a large amount of contrast medium.[6] If the criteria for a simple renal cyst are met on either of these studies,

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cyst puncture can be performed. If a mass appears solid, angiography or surgery should follow.

Computerized Tomography—Computerized tomography is the newest technique for the evaluation of renal masses. In preliminary work on masses that meet the classic computerized tomographic criteria for simple renal cyst, the accuracy has approached 100%.[7,8] CT and ultrasound studies have comparatively equal accuracy rates in evaluation of renal masses although the 2 techniques assess different properties of the lesion.[9,10] Ultrasound evaluates the acoustic properties of the mass, while computerized tomography evaluates the attention of an x-ray beam by the mass. Since ultrasound involves no ionizing radiation and is considerably less expensive than computerized tomography, most centers prefer to use ultrasound as the initial imaging study of these lesions.

Cyst Puncture—Cyst puncture is considered a relatively definitive approach to renal masses with an accuracy that approaches 100%. The cyst puncture can be performed under either ultrasonic or fluoroscopic guidance. Complication rates using either technique are approximately the same.[11] Significant complications including hemorrhage, pneumothorax, and infection,[11] occur in less than one percent of patients. The cyst fluid should be analyzed as outlined in Table 2. A simple renal cyst contains clear fluid, has a negative cytology, a LDH level lower than normal blood levels, and no fat.[12] A hemorrhagic cyst or a cyst that has been infected previously may have an abnormal LDH level or fluid of abnormal consistency. Nonetheless, unless all the criteria for a simple real cyst are present on the analysis of the cyst aspirate, further evaluation such as angiography is indicated.

Table 2

CYST ASPIRATE

	Tumor	*Cyst*
Color	Turbid or Bloody	Clear
Cytology	Positive	Negative
LDH	Higher than Normal Blood Level	Lower than Normal Blood Level
Fat	Present	None

Since renal cysts are so common, and since the imaging techniques used to evaluate them are highly accurate, the routine use of cyst puncture recently has been questioned.[1] It is clear that children, patients whose renal masses are symptomatic, and patients with an increased risk for malignancy (such as people with Von-Hippel Lindow syndrome) need a full work-up including cyst puncture. Elderly adults with incidentally discovered renal masses that meet the imaging criteria for a simple renal cyst need not have cyst puncture.

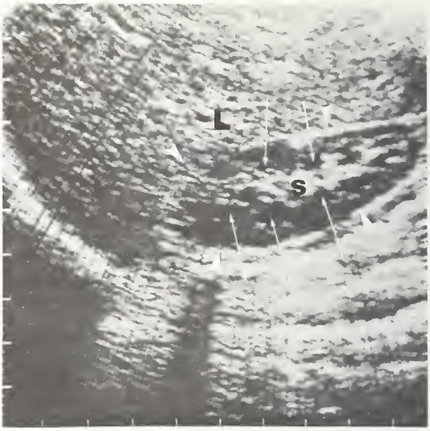

Figure 1
Normal renal ultrasound examination. Longitudinal parasagittal section through the right upper quadrant. The patient is supine. The liver (L) is seen anterior to the right kidney (arrowheads). Within the right kidney, the renal sinus (s) contains intense echoes. The cortex (including the septa of Bertin) contains low-level echoes. The medullary regions are seen as sonolucent zones (arrows) defined by the renal sinus, the cortex and the septa of Bertin. These pyramids should not be mistaken for renal masses.

Ultrasonography in Distinguishing Cyst From Tumor

The normal renal ultrasound examination (Fig. 1) shows excellent detail of the kidney. Gray scale ultrasound permits the definition of small parenchymal structures, such as cortex, medulla and arcuate vessels. Renal masses can be readily evaluated. In addition, ultrasound occasionally demonstrates renal masses that have not been appreciated on excretory urography and/or nephrotomography.[13,14] While ultrasound may be valuable in patient with a normal IVP and persistent hematuria, this modality generally should be regarded as complementary technique to the IVP in evaluating the kidney.

The ultrasonic criteria for renal cysts are summarized in Table 3. As shown in Figure 2, the typical renal cyst is echo-free (sonolucent), has a smooth back wall, and transmits sound well. The excellent transmission can be demonstrated by the presence of intense echoes behind the cyst as compared to other structures. To determine whether the gain settings are correct, the ultrasonologist can compare the renal cyst with such

Table 3

SONOGRAPHY OF RENAL MASSES

Cyst	*Tumor*
Sonolucent	Internal Echoes
Transmits Sound	Alternates Sound
Irregular Back Wall	Smooth Back Wall

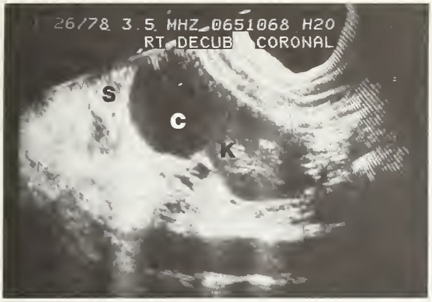

Figure 2
Renal cyst. Coronal sections through the left kidney with the patient in the right side down decubitus position. The cyst (C) is seen between the remainder of the left kidney (K) and the spleen (S). The cyst is echo free except for its anterior portion which contains reverberation artifact. The back wall is smooth and there are intense echoes behind the cyst.

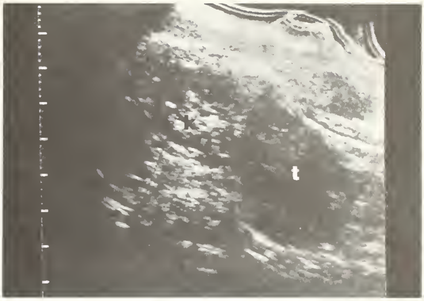

Figure 4
Hypernephroma. Longitudinal section through the right kidney (k) with the patient prone demonstrates a mass protruding from the lower pole of the kidney. This mass (t) has diffuse low-level echoes throughout. Hypernephroma may have echoes more intense or less intense than those of the normal renal parenchyma.

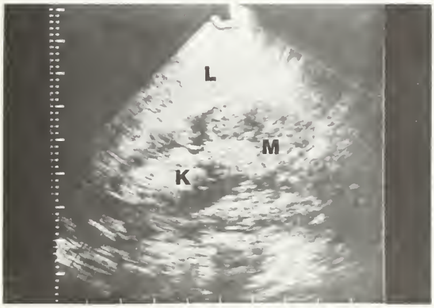

Figure 3
Hypernephroma. Longitudinal parasagittal section through the right upper quadrant demonstrates the right kidney (K) behind the liver (L). A mass (M) in the lower pole of the right kidney contains more intense echoes than the normal renal parenchyma. The mass has none of the features of a cyst.

fluid-filled structures as the gallbladder or urinary bladder. The acoustic properties of these 3 structures should be similar.

The smallest renal lesion that can be evaluated by ultrasound varies with the patient and the equipment. Contemporary gray scale equipment and high frequency transducers used on thin patients permit accurate evaluation of lesions as small as 1 cm.

The typical renal tumor has internal echoes which may be intense (Fig. 3) or low level (Fig. 4). There is some degree of attenuation to the ultrasound beam, and the echoes behind the tumor are generally less intense than those in front of the tumor. The back wall of the tumor may be irregular. In evaluating a renal mass, if all the criteria for a simple renal cyst are not present, further studies are indicated.

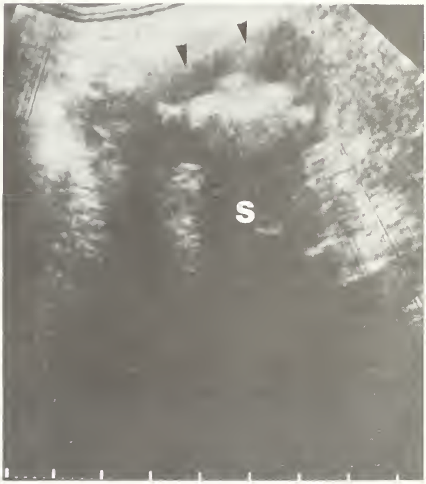

Figure 5
Longitudinal sections through the left kidney (arrowheads) of a patient with a staghorn calculus in the renal sinus. The staghorn calculus causes an acoustic shadow (S) distal to it.

When excretory urography shows a filling defect in the renal pelvis, ultrasound may be used to differentiate tumor from nonopaque stone.[15] A stone attenuates the ultrasound beam causing a sonolucent zone (acoustic shadow), distal to it; (Fig. 5) a tumor does not produce an acoustic shadow.

Other Diseases Causing Renal Masses

Polycystic Kidneys—Polycystic kidneys can be readily identified on ultrasound since they are imaged as large kidneys containing multiple cysts.[16] Approximately one third of these patients also have hepatic cysts, which are clearly demonstrated at sonography. The diagnosis of adult (dominant) polycystic kidney disease can be made even in childhood in the presymptomatic patient and can play a role in genetic counseling.[13 14]

Abscess—Abscesses appear as renal masses that may be completely sonolucent or contain internal echoes. A debris-fluid level may be present (Fig. 6). The differentiation from cyst or tumor may be impossible by ultrasound alone, but in the proper clinical setting, the diagnosis can be strongly suggested. Puncture of the mass under ultrasonic or fluoroscopic guidance is definitive.

Infected Cyst—Infected cysts are rare but present a problem in definitive diagnosis. A cyst that contains debris and/or a debris fluid level in a febrile patient, is probably infected and cyst puncture can be performed for further evaluation. Some infected cysts do not have internal echoes, but if infection is strongly suspected, cyst puncture is indicated in this situation, as well.

Acute Lobar Nephronia—Acute lobar nephronia (acute focal bacterial nephritis) appears ultrasonographically as a focal mass that disrupts normal corticomedullary definition and contains lower level echoes than normal renal parenchyma.[18] This diagnosis should be suspected in a patient with fever, flank pain, pyuria and a renal mass if the mass has these properties on ultrasound examination, appears solid on other imaging studies, and has abnormal activity on the gallium scan. The mass should resolve rapidly; serial ultrasound examinations can be used to follow the lesion to resolution. Failure of the lesion to resolve raises the possibility of an underlying tumor with superimposed renal infection.

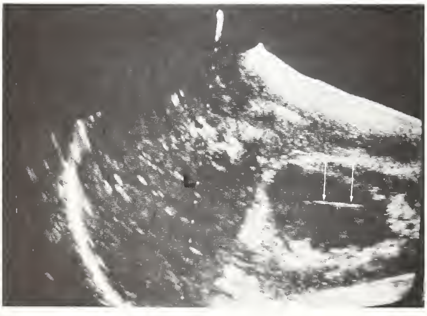

Figure 6
Longitudinal section through the right upper quadrant in a patient with an abscess. A debris-fluid level (arrows) is seen within a mass in the right kidney. This is typical of an abscess although it occasionally may be seen in a tumor which is necrotic.

Extended Evaluation of Renal Masses

Liver—Ultrasound is a highly accurate method of evaluating the liver.[18] The parenchyma of the normal liver appears as a homogeneous zone of low-level echoes. Metastases may cause either focal zones of lower than normal level echoes or zones of intense echoes. Either direct extension of right renal carcinoma to the liver or hematogenous metastases to the liver can be readily appreciated on ultrasound.

Evaluation of the Vessels—Tumors involving the renal veins, the inferior vena cava, or the right atrium, have been identified on ultrasound.[19 20] Every ultrasound examination of renal masses should routinely involve the evaluation of these structures, which can be readily identified on high quality scans.

Renal Biopsy—Skinny needle aspiration of renal masses for cytology is a safe procedure that can be done under ultrasonic or fluoroscopic guidance. The incidence of spread of tumor from this technique is negligible.[21] Nonetheless, surgery generally is performed for unequivocally solid renal masses. Needle biopsy of these lesions usually is performed only when a non-neoplastic cause is suspected in the differential diagnosis.

Angiomyolipoma—Most renal tumors do not have specific ultrasound characteristics. For example, Wilms' tumor (Fig. 7A) is similar in appearance to hypernephroma (Figs. 3 and 4). However, angiomyolipoma presents with extremely intense echoes (Fig. 8) due to its fat content.[22] When a mass with intense echoes is demonstrated, computerized tomography or plain film tomography should be performed. These studies can verify the diagnosis by demonstrating fat within the lesion. The demonstration of fat within a

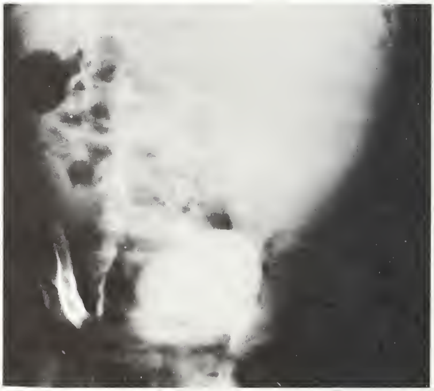

Figure 7A - Wilms' tumor.
Excretory urography shows a normal right kidney and no excretion of contrast medium from the left kidney. There is a mass occupying the left hemi-abdomen which on total body opacification was solid.

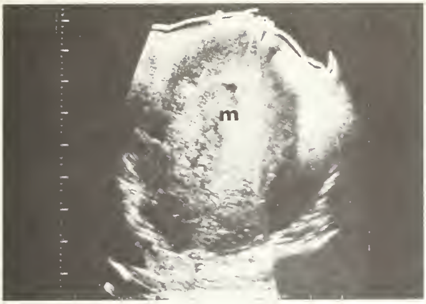

Figure 7B
Longitudinal ultrasound section through the left hemi-abdomen revealed a mass (m) to be solid in consistency with echoes throughout.

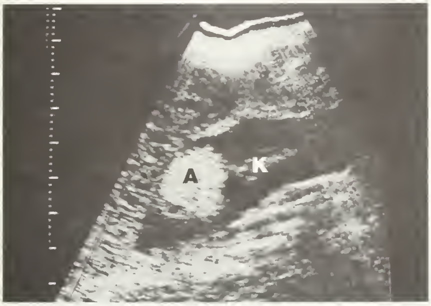

Figure 8
Longitudinal section through the right upper quadrant in a woman with a mass in the upper pole of the right kidney (K). The study was performed at a low gain so that there are no echoes in the renal parenchyma. The mass (A) contains intense echoes. This is typical of an angiomyolipoma. Computerized tomography showed fat within the mass. The mass was surgically removed and was an angiomyolipoma.

renal mass is indicative of either angiomyolipoma or occasionally lipoma.

Conclusion

The evaluation of renal masses should be individualized for a given patient. The clinical history should always be reviewed. Ultrasound is a technique complementary to standard uroradiologic studies and provides a comfortable, safe way to determine the solid or cystic consistency of renal masses.

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Methysergide Induced Mitral Valvular Insufficiency

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ABSTRACT—Methysergide, an agent used for the prevention of migraine headaches, is known to cause various cardiovascular fibrotic syndromes. The case history of a patient with histopathologically proven methysergide induced mitral regurgitation is reported. Mitral valve insufficiency secondary to methysergide induced mitral valve leaflet fibrosis may well be permanent as documented in this case with serial cardiac catheterizations. It may also be stable and asymptomatic, though later contribute to cardiac decompensation, particularly in the presence of other disease processes, i.e.—coronary artery disease. Possible etiologies of methysergide fibrosis are discussed.

Introduction

Methysergide has been effectively used for the prevention of migraine headaches, with adverse effects well defined.[1-14] Cardiac lesions associated with the use of this drug include aortic insufficiency,[7,8,15,16] tricuspid and pulmonary valvular insufficiency,[16,17] endocardial fibrosis,[7,15] coronary artery narrowing,[8,18] and constrictive pericarditis.[19] Mitral regurgitation, an entity most commonly due to rheumatic heart disease, has been well documented also.[3,7,8,13-17,20] This paper deals with methysergide induced mitral regurgitation hemodynamically worsening after development of moderately severe three vessel coronary artery disease.

Case Report

This 49-year old, white, male, engineer had taken methysergide for prevention of migraine headaches, 2-6 mg per day, continuously for 30 months in 1965-1968. In February, 1968, at age 41, he presented with acute pulmonary edema. No previous history of rheumatic heart disease was known. There was no history of chest pains or preceding symptoms. The patient smoked 1 pack of cigarettes per day and drank 3-4 bottles of beer daily. Examination at the time revealed bibasilar rales, and a grade 3/6 apical holosystolic murmur radiating to the axilla. No murmur was heard on a routine physical exam several years earlier. Chest x-ray revealed pulmonary edema, and electrocardiogram revealed sinus tachycardia. The patient readily responded to oxygen therapy alone and methysergide therapy was discontinued.

The patient remained totally asymptomatic and in May, 1968 was referred for cardiac catheterization. At that time, a grade 3/6 pansystolic murmur was heard in the left axilla. Chest x-ray was normal. Right and left sided pressures were normal, other than a left ventricular end diastolic pressure of 16 mm Hg. On angiography, grade 3-4+ mitral insufficiency was noted, with no angiographic evidence of rheumatic valvulitis, mitral stenosis, aortic valve abnormality, or primary myocardial disease. Coronary arteries were normal except for slight narrowing of the proximal right coronary artery.

The patient was well for the next 8 years, until October, 1976, when he presented in acute pulmonary edema. There was no history of chest pain, palpitations, or other preceding symptoms suggestive of heart failure. The patient was on no medications, and had continued using small amounts of alcohol and tobacco. Examination revealed bibasilar rales, and a grade 3/6 holosystolic apical murmur radiating to the left axilla. Electrocardiogram revealed sinus tachycardia and poor R wave progression across the precordial chest leads. The patient improved rapidly with oxygen, digitalis, and furosemide therapy. Serial cardiac enzymes and electrocardiograms revealed no evidence of acute infarction.

Echocardiogram revealed normal chamber sizes, septal and posterior wall motion, and aortic valve, but abnormally thickened anterior and posterior leaflets of mitral valve with decreased motion and no prolapse. Cardiac catheterization revealed normal left and right sided saturations and pressures, other than a left ventricular end diastolic pressure of 15 mm Hg. The left ventriculogram revealed a small area of apical dyskensia with otherwise normal size and excellent contractility. The left atrium was of normal size, and 3-4+ mitral regurgitation was again noted. Three vessel coronary artery disease was demonstrated, with a 90%

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tight proximal left anterior descending lesion, an 80% left circumflex lesion, and a 60% proximal right coronary lesion.

The patient was discharged on digoxin, and was readmitted one month later for triple coronary artery bypass grafts and porcine mitral valve replacement. At surgery the mitral valve was noted to have anterior and posterior commissure fusion with thickened cusps and subvalvular fusion. The patient had a satisfactory postoperative course complicated only by an episode of atrial flutter requiring D.C. cardioversion. One year postoperatively, the patient was without signs or symptoms of angina or heart failure.

Pathology

Gross examination of the surgical specimen revealed a largely intact mitral valve with attached chordae tendinae and small portions of papillary muscle. The inner circumference of the valve measured 6 cm. The valve leaflets and chordae tendinae were thickened; some of the latter were noted to be fused. Histologic examination revealed a uniform avascular layer of collagen over the valve leaflets and chordae tendinae. A Verhoeff's elastic tissue stain revealed no elastic tissue in the avascular surface layer. This layer was clearly demarcated by elastin from the underlying valve leaflet and chordae tendinae (Figure 1). These histopathologic changes are similar to those previously described in association with methysergide administration.[15, 17, 20] Histologic changes characteristic of rheumatic valvular disease were not seen in this specimen.

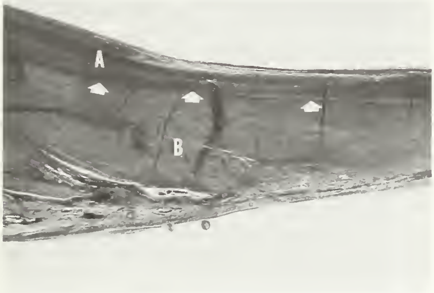

Figure 1
Section of mitral valve showing collagenized surface layer (A) sharply demarcated by elastin (arrows) from underlying valve leaflet (B). (Verhoeff's elastic tissue stain, X 10)

Discussion

This patient presented at age 41 after 30 months use of methysergide with acute pulmonary edema and a new murmur of mitral regurgitation. There was no history of rheumatic disease. Cardiac catheterization revealed mitral regurgitation, but essentially normal coronary arteries and chamber sizes. The patient was then totally well in the ensuing 8 years without medication until he presented with a second episode of acute pulmonary edema. Subsequent study again demonstrated mitral regurgitation with normal chamber sizes, but moderately severe three vessel coronary artery disease. Triple coronary artery bypass surgery and mitral valve replacement were performed. Histopathologic examination of the valve revealed changes characteristic of methysergide induced valvular fibrosis.

In this patient, mitral valve regurgitation secondary to methysergide therapy persisted following discontinuance of the drug. Munroe, et al suggest that aortic lesions are frequently reversible following discontinuance of methysergide, whereas mitral lesions tend to persist.[20] Bana et al indicated that in a large number of patients with valvular fibrosis secondary to methysergide improvement frequently occurs after the drug is discontinued.[15] The improvement in methysergide induced fibroses of all kinds following drug cessation seems generally to be the case, though sporadic cases have been reported to the contrary.[21]

The course of our patient's valvular heart disease is atypical for that of rheumatic heart disease. Despite heart failure, the presence and persistence of normal left atrial size and pressures, absence of arrhythmias and conduction defects, and lack of other valvular abnormalities, lend credence to the histopathological diagnosis of methysergide induced valve fibrosis. The history also suggests a nonprogressive aspect to the methysergide lesion following discontinuance of the drug, as opposed to the ongoing process in a rheumatic valve. Of interest, therefore, is the etiology of the patient's cardiac decompensation after 8 asymptomatic years. One must speculate that the coronary artery disease, now present but absent 8 years earlier, was responsible, at least in part, for his heart failure perhaps via papillary muscle dysfunction, and that the second episode of pulmonary edema was a clue to progressive ischemic heart disease superimposed on stable valvular disease.

Multiple etiologies have been offered to explain the fibrotic lesions associated with methysergide administration. The migraine syndrome in and of itself is not associated with fibrosis.[22] The current and most popular explanation for the fibrotic syndrome may be attributed to the drug's anti-serotonin effect. It is postulated that methysergide binds to serotonin receptors, thus displacing serotonin. The increased level of free serotonin is postulated to cause stimulation of fibroblast growth.[3, 7, 8, 22, 23] Thus, in carcinoid syndrome, characterized chemically by an elevated serotonin level, fibrosis of valvular cusps and endocardium is seen. However, in contradistinction to methysergide induced valvular disease, carcinoid causes primarily right-sided valvular fibrosis, presumably due to inactivation of serotonin by monoamine oxidase in the lungs, sparing the left-sided structures.[8, 24–26] Also, attempts at reproducing the syndrome with administration of serotonin, bradykinin, and dopamine in animals have been unsuccessful, thus raising a question of whether these substances are merely co-factors or bystanders in the fibrotic process.[23] Another theory is that methysergide itself has fibrotic potential, though this has never been reproduced in animal studies.[3,27] Several other theories are offered: collagen or autoimmune-inflammatory disorders being induced by methysergide,[3,7,8,13,14] prolonged vasoconstriction with venular dilatation and leakage of protein-rich fluid and formation of fibrocollagen,[3,7,14] abnormal metabolism of methysergide in sensitive individuals,[22,28] and mast cell degranulation secondary to methysergide with resultant local inflammation.[3,7,8]

Other side-effects ascribed to the use of methysergide include gastrointestinal disturbances, weight gain, edema formation, arterial and venous vasoconstriction and fibrosis, fibrosis of retroperitoneal and pleuropulmonary areas, and CNS disturbances—vertigo, insomnia, depression, and hallucinations.[1,3,4,5,7,8,9,13,15] The aforementioned adverse effects imply a list of contraindications to the use of the drug, i.e., vascular disease, valvular heart disease, fibrotic syndrome, hepatic disease and renal disease. The development of a new cardiac murmur should prompt the examiner to discontinue use of the drug. Interrupted methysergide therapy with drug free intervals has been recommended.[15]

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Non-Typable Hemophilus Influenzae Sepsis in a Child

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In 1931, Dr. Margaret Pittman[1] divided Hemophilus influenzae into two categories based on the presence or absence of a capsule. Those without a capsule were nontypable while those with a capsule were subdivided into six types (a, b, c, d, e, f). Since that time most serious pediatric infections have been caused by typable strains, usually type b. In this communication, a case of invasive disease produced by nontypable H. influenzae is presented emphasizing the importance of typing these organisms.

Case Report

An 8-year-old boy was admitted to Hartford Hospital because of head trauma secondary to a two story fall. Two days prior to admission he had been diagnosed and treated (penicillin 250 mg. qid) for otitis media.

On admission he was unconscious. Vital signs were normal except for a blood pressure of 130/90 mm Hg. He had a right parietal bruise and a fixed and dilated right pupil. The left ear drum was normal while examination of the right drum revealed an acute otitis media which had been diagnosed two days prior.

The patient was taken to the operating room where a right subdural hematoma was evacuated and therapy was begun with intravenous mannitol, dexamethasone, phenytoin sodium, and oxacillin. Eighteen hours following the operation the patient's temperature spiked to 41.7°C. Blood cultures at this time were positive for H. influenzae non b (sent to the Center for Disease Control and found to be nontypable). Also an endoctracheal culture, urine culture, and chest x-ray were negative. Ampicillin IV was begun when the positive blood culture was reported. The IV Ampicillin was continued for a total of two weeks. The patient gradually improved and repeat cultures of the blood, sputum, and CSF were negative for H. influenzae.

Comment

In our patient the nontypable H. influenzae could have originated from the middle ear or upper respiratory tract. H. influenzae is commonly found in the upper respiratory tract of children. Using selective media Kilian et al[2] found H. influenzae (88% nontypable) as part of the nasopharyngeal flora in half of the 130 children whom they cultured. H. influenzae has been shown to cause otitis primarily in the four year old and under age group;[3] [4] however, in more recent studies H. influenzae has been recovered in acute otitis from patients five and older.[5] [6] Howie et al[5] recovered H. influenzae in 31 of 182 children whose ages were 5 to 13; while Schwartz et al[6] recovered H. influenzae in 21 of 58 children whose ages were five through eight.

Serious infection with H. influenzae is usually caused by type b,[7] and infrequently other types (type e meningitis[8] [9] type f meningitis[10] [11] and type e septic arthritis).[12] Rarely has serious infection been reported with nontypable strains. Honig et al[13] reported five cases of H. influenzae pneumonia, four were type b and one was nontypable. This nontypable strain was recovered from the blood of a six year old girl with pneumonia and otitis. She was afebrile within 24 hours after initiation of IV Ampicillin. Granoff and Nankervis[14] reported a neonate in whom nontypable H. influenzae was recovered from blood, CSF, and a septic joint. This patient was treated with ampicillin for six weeks and recovered.

In conclusion, serious pediatric infections can be caused by H. influenzae nontype b. Only by typing the H. influenzae isolated in invasive disease will we be able to monitor changes in frequency, sensitivity (typable[15] and nontypable[16] have been reported resistant to ampicillin) and the disease patterns caused by different H. influenzae.

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Surgical Success with the Medical Failure of Pseudomembranous Colitis Treatment

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ABSTRACT—Two cases of pseudomembranous colitis are presented. The outcomes of the two patients were entirely different. Surgical intervention is recommended in the deteriorating patient with this disease. A review of the literature supporting this position is presented.

Pseudomembranous colitis can be a devastating problem. It commonly follows the use of certain antibiotics, but it can also occur spontaneously without antecedent antibiotics with or without impaired vascular perfusion. In the vast majority of cases, medical management is effective. This consists of withdrawal of the offending antibiotic and vigorous supportive therapy for maintaining fluid and electrolyte imbalance. Surgery must be considered in those cases that do not respond to the usual management and manifest deterioration of the patient's condition.

Our first experience was with a 51-year-old white female hospitalized because of diarrhea of two weeks duration, dehydration, fever, vomiting, and right lower quadrant pain. She had received a course of erthyomycin twice in the three months prior to admission for lower respiratory infection. The diarrhea was profuse and watery; blood and mucous were noted only once. Abdominal x-rays demonstrated bowel wall edema. The white count was 12,000 with 55 polys and 28 stabs. Sigmoidoscopy and rectal biopsy were consistent with pseudomembranous colitis (PMC).

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On the morning of the second hospital day, she became hypotensive and developed tachycardia; the white count rose to 51,000 with 60 polys and 30 stabs. She was treated with fluids, colloids, steroids, antibiotics and vasopressors. She responded temporarily. Twenty-four hours later, however, her condition began to deteriorate despite vigorous support of her cardiac, vascular, respiratory, renal and endocrine systems. Her abdomen remained distended and diarrhea persisted until her demise on the seventh hospital day. Her autopsy showed extensive PMC of the entire colon plus other organ system failure.

Our second patient with PMC was a 61-year-old white female hospitalized complaining of diarrhea of 4-days duration and left lower quadrant pain. The diarrhea was very watery and no blood or mucous were noted. Her medications included lomotil, donnatol and nitroglycerine. There was no history of antibiotic therapy. On admission, she had a tachycardia and her blood pressure was palpable at 100. She had direct and rebound tenderness in the left lower quadrant. White count was 15,000 with 32 polys and 49 stabs. Abdominal x-rays were normal.

Shortly after admission, her temperature rose to 103, and she was treated with nasogastric suction, IV fluids and antibiotics for presumed diverticulitis. Barium enema (see Figure 1) and rectal biopsy (see Figure 2) followed and these were consistent with PMC.

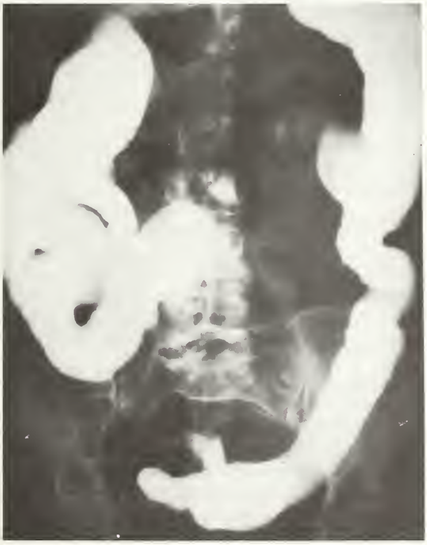

Figure 1

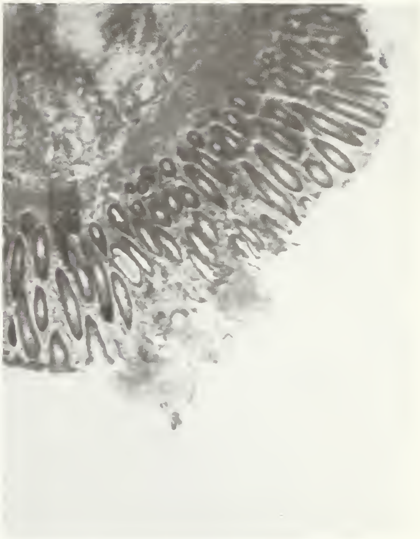

Figure 2

Her condition deteriorated over the next 36 hours as the abdomen became silent and distended. X-rays showed thumb-printing and progressive dilatation of transverse and sigmoid colons. Temperature and white count remained elevated, urine output declined, watery stools were almost continuous and gram positive rods were isolated from blood cultures. These later proved to be clostridium paraputrificum (see Figure 3). Because of her steady deterioration, a colectomy was performed.

At operation, the large bowel was thickened, edematous and dilated. Surprisingly, no perforations or serosal exudates were seen. A subtotal colectomy with ileostomy and Hartmann's pouch was performed. The patient was treated intra-operatively and post-operatively with large doses of intravenous penicillin and chloramphenical. Cultures obtained at surgery revealed the presence of both clostridium perfringens and another clostridium species.

Post-operatively she made a dramatic recovery (see Figure 4). She defervesced immediately and remained afebrile for the remainder of the hospitalization. Her confusion cleared, ileostomy functioned and she tolerated a diet. Proctoscopy prior to discharge showed healing of the rectal pouch.

She subsequently had an ileoproctostomy and is now at home with good bowel function.

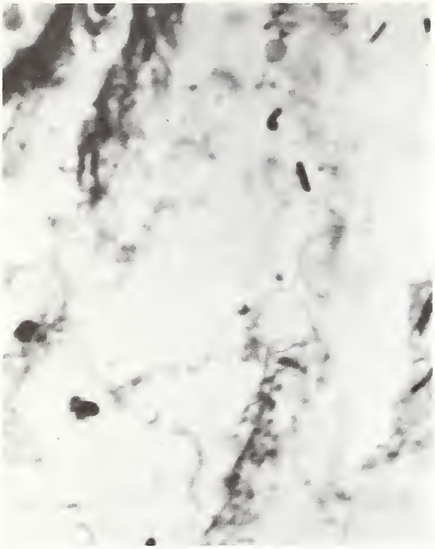

Figure 3

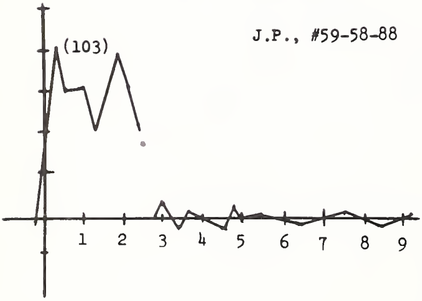

Figure 4

Discussion

PMC has been known for over 50 years and was initially thought to be secondary to poisons and irritants. Subsequently it has been associated with staph infection, obstruction, uremia, CHF and ischemia. To date, there is no consistent etiologic agent known, suggesting multifactorial pathogenesis. Mortality was in the 50 to 75% range and resulted from severe fluid and electrolyte imbalance and septic shock.

Surgery was not advocated because this lesion was potentially reversible and if a patient survived, bowel function would return to normal and the patient would not likely have a recurrence.

In contradistinction to this devastating form, the current medical and surgical literature contains numerous reports of PMC induced by antibiotics, especially clindamycin and lincocin. This drug-related type appears to have a better overall prognosis, but can become life threatening. In his excellent review Fekety describes what is considered the etiologic agent, C. difficile, and recommends oral vancomycin as the therapy of choice.

In a prospective study Tedesco reports a 21% incidence of diarrhea and 10% incidence of biopsy proven PMC following the use of clindamycin. There was zero mortality in this series and treatment consisted of withdrawing the antibiotic and supportive measures.

Occasionally, patients with antibiotic induced PMC develop signs and symptoms of an acute surgical abdomen. Tedesco reports on another series of 42 patients in which eight developed fever, leukocytosis and severe abdominal pain in addition to the usual diarrhea and cramps. One required an ileostomy for intractable diarrhea and the rest responded to supportive measures. Again, no mortality was reported.

Boyd and DenBesten[4] have reported two cases of antibiotic induced PMC which progressed to near fatal situations despite aggressive medical management. In both cases, the diagnosis was proven by sigmoidoscopy, dilation of the colon was demonstrated and patients were hypotensive just prior to operation. Subtotal colectomy with ileostomy and sigmoid mucous fistula was performed. Both patients survived and had ileosigmoidostomy done at a later date.

Surgical intervention for idiopathic PMC was first reported by Jackson and Anders in 1972. The diagnosis was established on sigmoidoscopy preoperatively. The patient's condition had also deteriorated to a critical level and a dramatic improvement was noted following total colectomy and ileostomy.

Block makes the point that PMC should not be considered a self limiting lesion and can progress to toxic megacolon and perforation or hemorrhage, like any other non specific colitis. He also has performed a subtotal colectomy on a patient with established PMC which had progressed to contaminated ascites, hemorrhage and toxic megacolon with perforation. The patient survived and is doing well.

Block has recently reported a series of patients who underwent emergency colectomy for complications of inflammatory bowel disease. These complications included: toxic megacolon, massive hemorrhage and fulminant disease. He advocates proctocolectomy for patients with known disease and have massive hemorrhage. Subtotal colectomy is performed for

Crohn's disease with a spared rectum, poor risk patients with fulminant disease and patients with toxic megacolon with or without perforation.

The classical sigmoidoscopic picture of PMC is pale yellow plaques adherent to an edematous hyperemic mucosa. Microscopically, the plaques tend to consist of fibrin, mucous, white cells, and occasionally bacteria. They occur as islands surrounded by relatively normal mucosa. Increased numbers of mucous filled distended goblet cells are also seen.

PMC, ischemic, ulcerative and Crohn's colitis may all present in a variety of ways, ranging from mild to fulminant and have overlapping symptoms. The key to distinguishing PMC from the others is in the sigmoidoscopic appearance and rectal biopsy.

In conclusion, the management of PMC should focus on early diagnosis via sigmoidoscopy and rectal biopsy. The offending antibiotic—if present—should be withdrawn, adequate hydration and electrolyte balance maintained, oral vancomycin therapy instituted and abdominal distension monitored by periodic girth measurements and/or plain films for bowel dilation. In the patient who does not respond to these measures, shows a progressive deterioration in fluid and electrolyte balance; or develops more fulminant disease, surgery can be lifesaving. Subtotal colectomy with ileostomy and either sigmoid mucous fistula or Hartmann's pouch appears to be the procedure of choice as our patient and those reported previously have all shown dramatic recoveries following this procedure. In all cases the rectal segments have shown healing allowing for subsequent re-anastomosis.

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Americans Want More Say On Risky Drugs

Many Americans feel that the decision to take potentially risky new drugs should be left to doctors and patients themselves, not to the government, according to a study by Clark University researchers. Earlier this year, nationwide telephone interviews of 1,514 randomly selected adults were conducted by the university's Public Affairs Research Center (PARC) under a grant from the Pfizer Corporation. According to the findings, 90% of Americans are interested in some level of government drug regulation but 73% thought a group other than the government should have the final say on whether or not a drug should be available. "The preferred alternative appears to lie in the area of informed consent," said PARC director John Blydenburgh. Of the surveyed group, 62% place the most trust in their doctors as a source of information on new drugs, compared with 27% who named the FDA, and 7% who named the company that made the drug.

—*Modern Medicine,* Nov. 15-Nov. 30, 1979

Genetic Knowledge of Connecticut Pediatricians: Implications for Continuing Education

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ABSTRACT—The genetic knowledge and attitudes of Connecticut pediatricians in practice and training were surveyed by questionnaire and correlated with their backgrounds and educational preferences. Fifty-five percent responded to the questionnaire. Answers to 18 factual questions on neonatal screening, prenatal diagnostic and chromosome tests showed better knowledge of more established tests and correlated significantly with decade of graduation from medical school. Practitioners graduating in 1960-1969 scored better than successively earlier graduates and also better than housestaff graduating in 1970-1975. Five reasoning questions on recurrence risks, which were less well answered, showed a similar correlation with decade of graduation.

Practitioners considered congenital malformations, chromosome disorders and patterns of inheritance all to be important to their practice, despite poorer performance on the risk of inheritance questions. Journals, conferences, specialty texts and consultations ranked high as continuing education vehicles.

We conclude that current medical training does not prevent areas of weakness in formal genetic analyses, and that recent genetic advances require several years to become generally known to practitioners.

Continuing medical education should focus on areas of demonstrated weakness, using preferred learning modes.

Clinical genetics has become much more relevant to the mainstream of medical diagnosis and patient management.[1] The swift pace of advances in biochemical and chromosomal genetics[2] has opened up new approaches to previously hopeless problems, including new diagnostic techniques, and the development of family-oriented genetic counseling[3] and fetal testing for genetic disorders.[4] Genetics epitomizes the load of increasing medical knowledge with which physicians have to keep abreast.[5] [6]

Genetics is particularly relevant to pediatricians, who are in a pivotal position for initiating diagnosis, treatment and counseling of many genetic disorders that appear in infancy or childhood. In order to assess the strengths and weaknesses of the genetic knowledge of this group of primary care physicians, we surveyed all pediatricians in Connecticut.[7] The survey had three objectives: to assess pediatricians' practical and theoretical knowledge in genetics; to correlate this knowledge with training, type of practice and learning habits; and to stimulate the awareness of genetics among these pediatricians, so that the survey itself might be educational. From the tests results we hoped to define areas of genetics in which knowledge needed upgrading and to recommend possible remedies.

Methods

Studied were physicians classified as pediatricians in 1974 with the Licensing Division of the Connecticut State Health Department. After eliminating those who had no clinical responsibilities, moved out of state, retired or died, we identified 374 pediatricians (called "Practitioners"). With the cooperation of directors of the six pediatric training programs in fifteen Connecticut hospitals, 117 housestaff were

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identified (called "Residents"). These groups constituted the study population of 491 pediatric physicians.

A self-administered questionnaire,* pretested on geneticists and other non-pediatric clinicians, asked 19 factual questions about diagnostic tests for genetic disorders and 7 reasoning questions about analysis of recurrence risks. A second section inquired about the respondents' opinions on genetic issues, their type of practice, and their medical training. The final section requested their perception of the importance of six areas of genetics to their practices and their ranking of eight continuing education options. Explanatory notes to all knowledge questions were available upon request. Confidentiality was preserved by coding individual responses. The study was endorsed by the Hezekiah Beardsley Society of the Academy of Pediatrics in Connecticut and approved by the Human Investigation Committee of Yale School of Medicine.

Responses to knowledge questions were graded with a score of one point for each correct answer. With a DATATEXT program,[8] percentage correct on factual and reasoning questions was compared with training, attitudes and preferences of Practitioners and Residents. Demographic characteristics of nonrespondents were compared with those of respondents.

Residents were excluded from the appraisal of attitudes and preferences. A four point system was used to score the importance of genetics to practice and continuing education preferences. Respondents were asked to rank four out of eight choices for keeping up with advances in general pediatrics and genetics.

Results

Characteristics of Respondents

Responses were received from 218 Practitioners (58 percent) and 52 Residents (44 percent), yielding an overall response rate of 55 percent.

Nonrespondent differed significantly from respondent Practitioners only in the proportion who were board certified in pediatrics ($p < .01$). There were no significant differences in sex, decade of graduation from medical school, medical school location, or geographic area of practice (Table 1).

Among the respondents, 74 Practitioners were in solo practice, 92 were in groups, and 33 were hospital-based, of whom 28 had full-time university appointments. The age and years in practice of Practitioners correlated closely with decade of graduation. Subsequent analyses are reported only for decade of graduation. There were more females and more non-European foreign medical graduates among the Residents than among Practitioners. Thirty percent of Residents had just started pediatric training this summer.

Table 1

DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS AND NON-RESPONDENTS

	Respondents		*Non-Respondents**
	Practitioners (N=218)	Residents (N=52)	Practitioners (N=156)
Sex: Male	192	39	120
Female	26	13	36
Decade of Medical School of Graduation			
Before 1940	17		17
1940-1949	43	—	30
1950-1959	66	—	39
1960-1969	87	6	65
1970 and later	5	46	5
Country of Medical School			
USA/Canada	179	34	132
Europe	18	2	
Other	21	16	24
Board-Certification			
Certified	178		104
Not Certified	40	52	52
Full-Time Academic Faculty	28	—	32

*No demographic information was obtained on non-respondent Residents

Results of Genetics Tests

Answers to factual and reasoning questions are displayed in Tables 4 and 5. Percentage of correct answers for factual (77%) and reasoning (51%) questions were calculated after exclusion of the athyreotic cretinism question and the last two reasoning questions, which were poorly answered and of doubtful fairness. Perfect scores were registered by 17 respondents for factual questions and by 3 respondents for reasoning questions. Twelve respondents failed to score any points on the reasoning questions.

Opinions of Respondents

Ninety-two percent of respondents approved of antenatal testing in principle. Four Practitioners opposed it because they disapproved of abortion. If the subject of antenatal diagnosis were brought up prior to a pregnancy, 81 percent of Practitioners would discuss it with the prospective mother; the others would refer her to a geneticist (16 percent) or to an obstetrician (2 percent) without discussion.

For an infant with features of Down's syndrome born to a 30 year old mother, 96 percent of Practitioners would recommend chromosome testing of the infant; 54 percent would test both parents as well. In contrast, a geneticist would have tested only the infant.

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*The questionnaire is published in Hsia, Y.E., Bucholz, K.K., and Austein, C.F. "Genetic knowledge of Connecticut pediatricians and obstetricians: implications for continuing education," in Porter and Hook (ed) *Service and Education in Medical Genetics* (New York Academic Press, 1979)

Eighty-nine percent of Practitioners indicated young parents of a child with Down's syndrome should be informed of the diagnosis within the first week after birth, and 94 percent felt the pediatrician should be the informant. Two Practitioners added that the obstetrician should participate. For explanation of recurrence risks to such a family, 63 percent of Practitioners would do it themselves, 5 percent would include the geneticist, and 25 percent would assign the task to a geneticist. Fourteen Practitioners would include, while three would leave it to, the obstetrician.

One hundred fifty-three Practitioners estimated the proportion of serious genetic diseases was between 1 and 3 percent of their patients. Eighty-two percent indicated that they had informed all or most of these families about the recurrence risks of these conditions. Half claimed they discussed a genetic problem at least once a month with their colleagues.

Correlation of Knowledge Scores with Demographic Variables

There was significant correlation of both factual and reasoning scores with decade of graduation from medical school ($p < .001$) (Figure 1). The trend of better scores with more recent decade of graduation did not hold for those graduating in the 1970's, a group consisting almost exclusively of Residents. Knowledge scores did not correlate significantly with sex, length of training, sub-specialization, whether board certified, type of practice or academic status. Foreign medical graduates scored lower than other graduates among both Residents and Practitioners. Board-eligible 1960-1969 graduates scored higher than their contemporaries, but these differences were not significant.

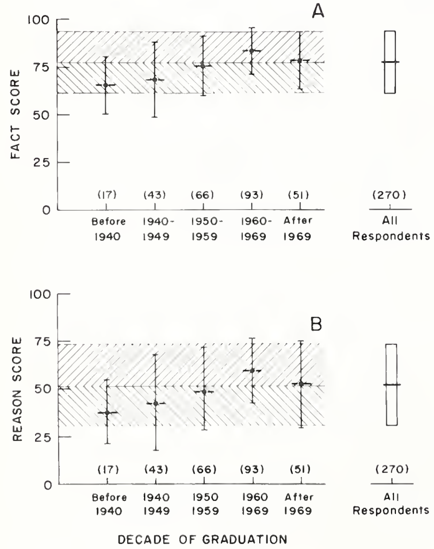

Figure 1

Knowledge scores of practitioners, grouped by decade of graduation. The mean ± 1 standard deviation for each group of graduates is plotted against FACT score (figure 1a) and REASON score (figure 1b). The numbers in parentheses refer to the number of respondents in each category.

Attitudes Toward Genetics and Continuing Education

Practitioners viewed patterns of inheritance and congenital malformations as highly important to their practices. Chromosomal abnormalities, genetic counseling, metabolic disorders, and prenatal diagnosis followed in that order (Table 2). There was no correlation between perceived importance of areas and scores in those areas.

Preferences for continuing education in general pediatrics matched closely those for genetics (Table 3). Medical journals ranked high in both areas, followed by conferences and rounds, consultations and specialty texts. Regional conferences and general texts ranked lower, while tapes and drug company information were barely ranked at all. Those who placed journals highest had better scores than those who ranked journals lower.

Table 2

IMPORTANCE OF SIX AREAS IN CLINICAL GENETICS TO PRACTITIONERS (N-216)

	*Scores**
Congenital Malformations	533 (55)
Inheritance Patterns	545 (49)
Chromosome Abnormalities	464 (44)
Genetic Counseling	457 (40)
Metabolic Diseases	444 (32)
Prenatal Diagnosis	349 (28)

*Respondents were asked to indicate the importance of these areas to their practice, points were awarded according to importance (4 for "very important", 3 for "important", 2 for "somewhat important", 1 for "slightly important" and -5 for "not important"). The numbers in parentheses are the number of "very important" responses.

Discussion

Study Design

There are limitations to a one shot questionnaire survey, especially when directed toward a busy professional population. Our response rate of 55 percent compares favorably with that obtained by others.[9] [10] Inclusion of all Connecticut pediatricians avoided sampling bias. Access to key demographic data from the State Licensing Bureau allowed comparison of respondent and nonrespondent Practitioners, demonstrating nonrespondents were less likely to be board certified than respondents. Nonrespondents were unlikely to be either more knowledgeable about genetics or more receptive to genetic education. Rather, it is more likely that those who felt confident of superior performance on the test would have returned the questionnaire.[11] Thus, our results should represent an overestimate, rather than an underestimate, of the level of genetic knowledge of Connecticut pediatricians.

Respondents were at liberty to consult resources in answering questions, although the paucity of perfect scores suggests that this did not occur. Still, if the questionnaire had stimulated discussion or reading about genetic problems, this would have served our third objective, that of promoting pediatricians' awareness of genetics. We feel our study is an accurate, albeit limited, measure of the knowledge and attitudes of our respondents.

We may not be able to generalize from our study to other pediatricians and primary physicians, because Connecticut pediatricians, judging from the proportion who are board certified (78 percent), may represent a better qualified physician group than exists nationwide, where 70 percent are board certified.

Continuing education preferences for genetics corresponded to those cited for general pediatrics and suggest that learning modes might not differ for other medical specialty fields. A possible exception to this might be preferences for consultations, which depend on accessibility of, and satisfaction with previous, consults. In Connecticut, at the time of the survey, clinical genetics consultation services had been available at two medical schools for the last five years.

Residents were included in the study to assess whether recent medical graduates would be more knowledgeable about genetics due to increased basic genetics in medical school education and retention of recently taught material.[14] The comparison is weakened by the finding that a large proportion of Residents had graduated from foreign medical schools. However, our findings did not suggest more effective formal medical school training in clinical genetics.

Table 3

CONTINUING MEDICAL EDUCATION PREFERENCES OF RESPONDING PRACTITIONERS

	*Scores**	
	General Pediatrics (n=220)	*Genetics* (n=218)
Medical Journals	616 (106)	526 (82)
Hospital Conferences and Rounds	434 (37)	336 (34)
Specialty Textbooks	265 (16)	330 (28)
Consultations	261 (7)	350 (32)
Regional Conferences	209 (11)	172 (6)
General Textbooks	202 (23)	191 (10)
Teaching Tape Cassettes	52 (7)	33 (5)
Drug Company Information	11 (0)	7 (0)

*Respondents were asked to rank their top four preferences from this list. Points were awarded according to rank (4 for first, 3 for second, etc.) The numbers in parentheses are the numbers of first place rankings.

Genetic Knowledge

The knowledge questions addressed facts about diagnostic tests for conditions with which pediatricians should be familiar and recurrence risk situations likely to be encountered in practice. Poor responses to several questions prompted us to exclude them from analysis. Had these questions been included, our interpretation of the results would not have been altered.

Factual Questions

For the questions on neonatal screening, all but two respondents answered correctly about phenylketonuria. Two-thirds knew about testing for galactosemia, which had been in operation for five years in Connecticut. Only one-fifth knew about thyroid screening, which had not yet been started in Connecticut, although it was well-covered in the then current literature.[15] Since Practitioners were better informed than Residents about galactosemia (60 percent versus 46 percent correct respectively), but less well informed about hypothyroidism (19 percent versus 23 percent correct), it is probable that practical experiences with their own patients was a major determinant of Practitioners' knowledge. Residents, on the other hand, would have theoretical knowledge about these topics.

Two factors seemed to determine the responses to the prenatal testing questions. The first is that the longer a given procedure has been established, the more widely it is known. The second factor is that the expectation of diagnosing a disease prenatally is directly proportional to its perception as "genetic." Congenital heart disease, diabetes mellitus, and cleft lip and palate were regarded as medical disorders with little appreciation for their genetic components. Thus, few respondents indicated prenatal diagnosis was available. In contrast, achondroplasia, cystic fibrosis, phenylketonuria, and sickle cell anemia were generally recognized to be genetically-caused disorders with medical consequences, and the number of affirmative responses to availability of antenatal diagnosis increased.

Responses to indications for chromosome testing were a matter of judgment and were satisfactory. Nonetheless, 25 percent of respondents appeared to be ill-informed about the irrelevance of chromosomal testing in mucopolysaccharidosis.

Reasoning questions

Factual questions covered relevant topics in three major areas of genetics. Reasoning questions explored knowledge about recurrence risks, including possible new single gene mutations in autosomal dominant achondroplasia and X-linked recessive

Duchenne's muscular dystrophy; differences in recurrence risks for a single homozygous versus two heterozygous parents in autosomal recessive sickle cell disease; and risks of inheritance of multi-factorial Fallot's tetralogy increasing with the number of affected siblings. One-third of respondents correctly answered each of two questions pertaining to possible new mutations and only ten percent answered both questions correctly. The results demonstrated moderate command of rules governing Mendelian inheritance but poor appreciation of exceptions to these rules.

Table 4

FACT QUESTIONS ABOUT GENETICS

A. *Screening Tests*

Can mass screening tests on a drop of dried blood be used to test the following disorders in the newborn population?

	Yes	*No*	*Don't Know*	*Percent Correct*
Phenylketonuria	267*	2	0	99
Athyreotic cretinism	54*	144	68	—
Hemophilia	11	218*	37	81
Galactosemia	174*	47	45	64
	Mean ± 1 s.d. (excluding second question)			81±

B. *Prenatal Diagnosis*

Are tests *routinely* used in Genetics Centers for diagnosing the following conditions of the fetus in mid-pregnancy? (By "routinely used," we mean established procedures performed regularly.)

	Yes	*No*	*Don't Know*	*Percent Correct*
Achondroplasia	50	142*	68	.53
Cleft lip and palate	9	209*	44	.77
Cystic fibrosis	65	169*	31	.62
Diabetes mellitus	6	236*	23	.87
Down syndrome, trisomy 21	256*	11	3	.95
Fallot's tetralogy	2	236*	26	.87
Myelomeningocele	140*	93	32	.52
Phenylketonuria	82	149*	34	.55
Sickle cell anemia	53	171*	39	.63
Tay-Sachs disease	223*	25	20	.83
		Mean ± s.d.		.72 ± 15

C. *Chromosome Tests*

Are chromosome tests indicated for the following clinical situations?

	Yes	*No*	*Don't Know*	*Percent Correct*
Newborn infant with ambiguous genitalia	251*	13	3	.93
Newborn infant with multiple malformations	243*	19	7	.90
Child suspected to have cystic fibrosis	15	241*	12	.89
Child suspected to have mucopolysaccharidosis	43	200*	25	.74
Delayed puberty in a 16 year old girl	233*	26	11	.86
		Mean ± 1 s.d.		.86 ± .07

*Correct answer

Facsimile of FACT questions, with responses. One point was given for each correct answer; the mean score (the fraction of correct responses) is in the last column. The question on athyreotic cretinism was eliminated from further analyses.

Opinions

Respondent Practitioners claimed to be keenly responsive to families' genetic concerns. The majority felt that they had informed their families about known genetic problems. When confronted with hypothetical situations, almost all felt it was the pediatricians' responsibility to explain promptly about Down's syndrome to parents. Virtually no one was opposed to the offer of prenatal testing and most would discuss it prior to a subsequent pregnancy. Yet these opinions may not be predictive of physician performance. In another study, we found great discrepancy between what patients' families understood about the genetic aspects of congenital heart disease and what their physicians had intended to convey.[16]

The observation of the absence of a close liaison between pediatricians and obstetricians was disturbing, because together these specialists fulfill crucial roles in providing health care to mothers and children. Despite nearly unanimous approval of prenatal testing among our respondents, few Practitioners seemed to include obstetricians in their considerations.

Attitudes

It was not surprising that congenital malformations and chromosome abnormalities, conditions that are relatively common and easily recognized, were perceived as being important. Particularly noteworthy was the contrast between Practitioners' perception of the relevance of inheritance patterns to their practices and their poor test results in this area. This association of perceived need with weak knowledge merits the attention of continuing education programs. The low rank of prenatal diagnosis reinforced our impression that pediatricians and obstetricians did not share clinical responsibilities.

Preferences

The continuing education preferences of Practitioners for genetics were compared with the general pediatric learning habits. We believe the responses were an honest and accurate reflection of how Practitioners viewed their *preferences*, which does not necessarily correspond to how they best *learn*.[1] Poor responses on neonatal testing for hypothyroidism and prenatal testing for meningomyelocele, which received extensive exposure in medical journals in the two years prior to the survey,[15 18 19] revealed discrepancies between preferred means of learning and what is learned.

Table 5

REASON QUESTIONS ABOUT GENETICS

D. *Recurrence Risks*

For each of the following family situations, is the risk of recurrence of the condition in *future children* greater in situation a or situation b?

	a Greater	*b Greater*	*Equal*	*Don't Know*	*Percent Correct*
a. Fallot's tetralogy affecting *only one* child b. This condition affecting *two* siblings	13	144*	73	35	.54
a. Duchenne's muscular dystrophy affecting *only one* child b. This condition affecting *two* siblings	10	88*	147	20	.33
a. Sickle cell SS disease affecting *only one* child b. This condition affecting *two* siblings	11	69	177*	7	.66
a. Sickle cell SS disease affecting only one child b. Sickle cell SS disease affecting only a *mother* (father AA)	211*	20	18	17	.78
a. Achondroplasia affecting only one *child* b. This condition affecting only a *father*	60	71*	61	73	.26
(Risk for Down Syndrome) a. A 25-yr.-old mother whose child has trisomy 21, Down syndrome b. A 45-yr.-old mother whose child was normal	119	116	19*	11	
In a family with one child affected by trisomy 21, Down syndrome, and another child affected by meningomyelocele, which condition has the greater risk? a. Trisomy 21, Down's syndrome b. Meningomyelocele	125	72*	26	41	
		Mean ± 1 s.d. (excluding last two questions)			.51 ± .21

*Correct answer

Facsimile of REASON questions, with responses and mean scores for each question. The last two questions, considered to be unfair, were eliminated from further analysis.

Training

The reasoning section explored respondents' ability to apply basic genetic knowledge to clinical situations. Weak performances in this area might be due to inadequate medical school training in basic genetics or insufficient practical experience in analyzing patterns of inheritance. Our study suggested deficiencies in both training and experience of respondents. Although our results showed a trend of improving scores with more recent medical school training for Practitioners, our data indicated two additional influences, practical field experience and preparation for pediatric board exams.

Implications for Continuing Medical Education

Continuing education should be directed at correcting deficiencies in physician performance.[21] Federally mandated medical audit, through Professional Standards Review Organizations, monitors physician performance in the hospital setting. Assessment of physician performance in the community is more complex and difficult. Licensure, specialty certification, and participation in formal educational sessions are indicators of knowledge acquired, but not of performance. Knowledge may be a convenient surrogate for physician performance[10, 22, 23] in this manner: possession of knowledge is no guarantee that it will be applied, but absence of knowledge must result in substandard performance.

Our descriptive study attempted to define gaps in genetic knowledge and to poll preferences for continuing education. Our demonstrations of deficiencies in knowledge about genetic tests and recurrence risks have identified areas of potential weakness in performance. Our study suggests that formal medical education has not supplied current graduates with optimal genetic knowledge. Thus, for the future, physicians will continue to require refresher material in basic genetics as well as updated information on advances in genetics.

Remedies should reflect continuing education preferences of the target population. We have shown that our respondents prefer to rely on journals, conferences, specialty texts and consultations. Whether continuing education programs designed with these preferences in mind are effective in promoting knowledge, and more importantly, in modifying performance, is a key question that must be addressed by future research.

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Melanoma: A Multidisciplinary Overview of Current Concepts and Management

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Melanoma has attracted a disproportionate amount of investigation and interest in medical oncology, dermatology, surgery and tumor immunology. It accounts for 2% of fatal malignant disease in the United States and has historically been associated with a 40% mortality. The past few decades have witnessed a better understanding of the natural history of malignant melanoma, as well as improved management. This review will highlight several new aspects of malignant melanoma, as well as basic elements of an approach to management of this disease.

Melanoma arises from an abnormal proliferation of melanocytes. Melanocytes are pigment-laden cells normally distributed along the basal layer of the epidermis. They are often found in coalescent groups where they may comprise moles or nevi. Three common varieties of nevi are recognized:[1 2] the junctional nevus in which melanocytes are found above the basement membrane of the epidermis; the compound nevus in which melanocytes are present in the epidermis and the dermis; the dermal nevus in which melanocytes are located predominantly in the dermis. Approximately 60-70% of melanomas are now believed to arise from pre-existing nevi although past reports suggested an association in as few as 20-30%.[3] There is controversy regarding the malignant potential of the junctional nevus, while other types of nevi have no known malignant potential. Prophylactic excision of junctional nevi located in the genitalia, palms, nail beds and mucous membranes has been suggested, but this is not universally accepted.[4]

Certain pigmented lesions of the skin have a well documented malignant potential. Congenital nevi in general, and particularly the giant, hairy bathing trunk nevus, exhibit transformation in 1.8-13.7%.[5] Lentigo maligna is an acquired lesion most frequent on the face and sun-exposed surfaces of the elderly, and is also clearly associated with malignant transformation. When surgically feasible these premalignant lesions are best managed by complete local excision, without requirement of wide margin.

Benign pigmented lesions show order in color, symmetry of the border, and uniform surface characteristics, whereas malignant lesions often lack the regularity of these features. Malignant lesions may show a haphazard array of variable shades of red, white or blue, black or brown. Furthermore, areas of depigmentation intermixed with lesser shades of brown or black, or frank areas of gray or white in previously pigmented lesions, are suspicious and should be biopsied. The overall color pattern is often non-homogeneous and borders are frequently irregular or notched. Surface texture may be papular, nodular, or ulcerated; where macular, normal skin markings are often lost. (Figures 1-2). Any lesion that bleeds, ulcerates, enlarges, or varies its pigmentation over a period of time warrants close evaluation. This holds true in pregnancy as well, when changes may erroneously be ascribed to hormonal factors.

Suspicious lesions should be evaluated by either punch or excisional biopsy sufficiently thick to include the underlying subcutaneous tissues. Shave biopsy is contraindicated because often the full depth of the lesion cannot be appreciated. There is no documentation for the frequent concern expressed by patients and physicians alike, that incisional (punch) biopsy may disseminate this malignancy.[8] To the contrary—delay in establishment of histologic diagnosis is in our opinion a far greater risk.

The clinical appearance of melanoma is prognostically important, and every physician should be aware of its morphological features. Three commonly recognized biologically distinct patterns are lentigo maligna melanoma, superficial spreading melanoma, and nodular melanoma. These are well illustrated in a color atlas published in the New England Journal by Mihm *et al* in 1973,[6] and a more recent publication in this journal by some of us.[2] These morphological entities exhibit histopathological features that may provide a basis for understanding the differing

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biological behavior of melanoma. Lentigo maligna is characterized by presence of melanocytes which appear malignant *in situ* where they may remain confined for years. Lentigo maligna melanoma occurs when proliferation and invasion through the basement membrane occurs at some site in the large preexisting lesion of lentigo maligna. Superficial spreading melanoma initially exhibits a growth phase which is radial, or superficial, later in its course becoming vertically invasive and extending to the subcutaneous lymphatic and vascular channels of distant dissemination. Nodular melanoma from its inception exhibits a vertical pattern of growth, with early propensity for distant metastases. The location of melanoma is prognostically important, with primaries located on the more distal extremities more favorable than trunk or head and neck, perhaps because of the greater ease of assessing and treating draining lymphatics.

There are two widely accepted classifications which have proven useful in predicting metastatic potential and survival of patients with primary melanoma. They are based on the principle that the vertical extension of a lesion provides an index or microstaging of its aggressive potential. The best known of these systems is Clark's classification.[7 9] This system designates invasion of the skin by the strata through which the tumor has invaded.

Level I consists of *in situ* melanoma.

Level II shows invasion of the upper papillary dermis.

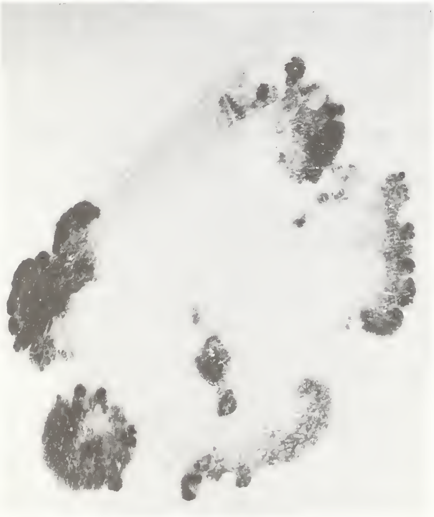


Figure 1
Superficial spreading melanoma with central regressive changes.

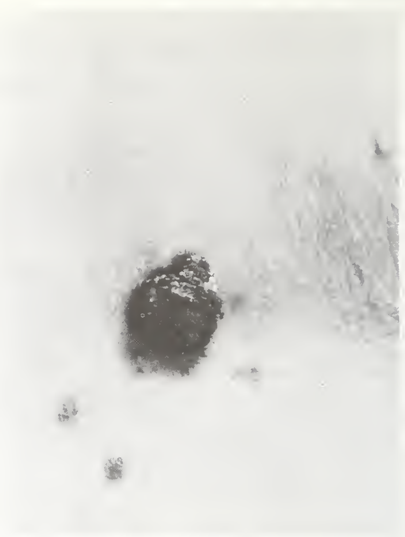


Figure 2
Nodular melanoma.

Level III lesions have invaded and filled the papillary dermis to the interface of the reticular dermis.

Level IV melanoma has invaded the reticular dermis.

Level V melanoma exhibits malignant cells penetrating into the subcutaneous tissues.

Table I
DISEASE FREE SURVIVAL BY CLARK'S LEVEL AT 5-9 YEARS IN TWO SURGICAL SERIES

	% Survival	
Level	*Cady (10)*	*Wanebo (11)*
II	86	100
III	67	90-82%
IV	67	71-60%
V	11	17

The Clark system is now complemented by a simpler micrometer system of measuring thickness from the granular layer (Breslow)[12 13 14] low risk is associated with Clark levels I and II, as with Breslow depth less than 0.76 mm.[15] Breslow depth appears linearly correlated with fatal recurrence, in contrast to the rapid increase of risk at Clark levels IV and V. Balch et al have compared the two primary microstaging systems, and thickness is the most powerful prognostic factor[15] (Figure 3).

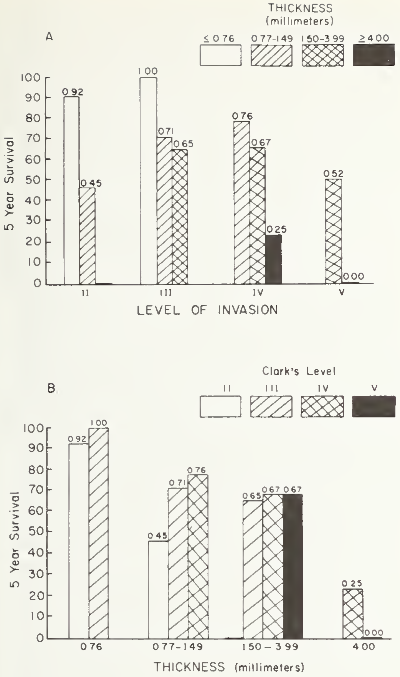
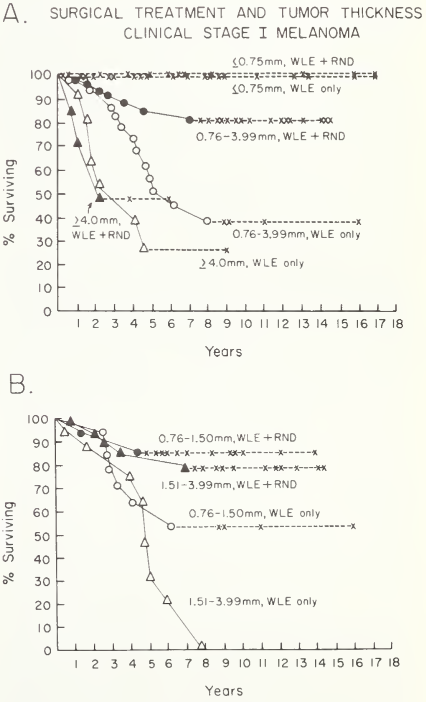


Figure 3 (A and B)
Five-year survival according to depth of primary, comparing Breslow's thickness and Clark's levels.

Clark levels may be interpreted with some latitude, and disagreement as to Clark level of particular lesions among pathologists is not infrequent.[13] Other biological factors that have been suggested as prognostic indices include sex of the parent,[16] although more recent multifactorial analysis indicates that this may be largely the result of a predominance of lower extremity primary melanoma in women, and truncal, head and neck primaries in men, with location of primary the more important factor.

Lymph node invasion is an overwhelmingly important prognostic factor, defining the difference between Stage II, with regional lymph node invasion, and Stage I or localized disease at the primary site and adjacent skin within 5 cm of the primary. The presence of distant metastatic disease, beyond the regional draining lymph nodes, defines a subset of patients with radically shorter median survivals, and is designated Stage III. As there is a significant difference between widespread soft tissue and cutaneous metastases, and visceral metastases to vital organs such as liver and brain, this last category of distant metastatic disease has in certain instances been subdivided further, to designate soft tissue metastases separately from visceral metastases, with their differing prognosis. Within the subset of patients with clinical Stage I malignant melanoma, who are at surgery found to have evidence of lymph node invasion, it appears that there still may be prognostic implication in the Breslow level of the primary.[17]

The accepted definitive surgical treatment for melanoma is wide local excision encompassing a margin of 3 to 5 cm and all subcutaneous tissue down to fascia.[18] In most cases, this dictates need of skin grafting, although exceptions may include the head and neck, where primary closure has been acceptable, at times utilizing flap rotation techniques.[19] Clinically involved regional lymph nodes (Stage II disease) are customarily resected completely. The advisability of


A. SURGICAL TREATMENT AND TUMOR THICKNESS
CLINICAL STAGE I MELANOMA

B.

Figure 4 (A and B)
Percent survival based on depth of primary, according to Balch, reference 15. WLE = wide local excision, RND = regional nodal dissection. By permission of Lippincott.

wide local resection has been debated for melanomas thinner than .76 to 1.0 mm, and it appears from recent literature that even with rather narrow margins, the risk of recurrence in such lesions is small.[15 38 39]

Controversy arises regarding the management of lymph nodes in clinical Stage I patients, where no palpable lymphadenopathy is detectable. Two large published experiences, including a prospective study by the World Health Organization in which patients with melanomas of the extremities were randomized to lymphadenectomy or control groups, failed to yield evidence supporting any value of elective lymph node dissection in prolongation of survival, when data was analyzed by sex, site of origin, histology, or thickness.[20] Furthermore, the rate of regional lymph node metastases and local recurrence was unchanged by prophylactic lymphadenectomy in this series. However, a major criticism of this study was that over 80% of patients entered in it were women, and lymphadenectomy yielded a low incidence of occult lymph node involvement (20%). Furthermore, levels of invasion were considered in aggregate, and there is evidence from a recent retrospective multifactorial study suggesting highly significant value of lymphadenectomy in discrete subgroups of primary melanoma, where thickness is 1.5 to 4 mm[21]. Another large prospective study carried out at the Mayo Clinic, has failed to support elective lymph node dissection in patients with clinical Stage I extremity melanomas, but has included an insufficient number to allow any statement for the subgroup with 1.5-4 mm thick lesions.[22]

The uncontrolled and retrospective suggestion that lymphadenectomy in the situation of clinical Stage I melanoma may benefit the patients has been derived from several surgical series in which patients found to harbor a single microscopic focus in one lymph node, or a solitary macroscopically involved node, experienced significantly improved survival by comparison with patients who were found to have multiple unsuspected pathologically involved lymph nodes (67% and 50%, respectively, compared to 15% at five years).[10 23] This favorable group which comprised 27 of 219 patients, may reflect sampling bias, or methods of pathological examination. Other indications for elective lymphadenectomy in the setting of protocol studies of new therapeutic programs in melanoma have included the definition of categories of high risk patients who might benefit from adjuvant therapy. The surgical stage of disease has been shown to be the most important predictor of survival after all other factors in multivariate analysis have been excluded. Otherwise, the further study of a role for lymphadenectomy in the treatment of melanoma awaits the development of more sensitive tests to define patterns of metastatic spread presurgically. Such tests as colloidal gold scanning[24] and tomographic gallium scanning which have recently become available in some cancer centers.[25] The course of melanoma metastatic to the skin or lymph nodes is subacute or chronic in most patients with median survivals of 4 to 10 years.[16] Visceral metastatic disease, especially as it involves the liver and central nervous system is associated with a more precipitous median survival of 3 to 6 months. There are a substantial number of patients who live many years despite progressive metastatic melanoma, in several of whom presumed preterminal visceral disease has subsequently regressed spontaneously, in association with the development of vitiligo. The prognostic and therapeutic implications of the development of vitiligo will be discussed later in the context of adjuvant therapeutic programs currently under investigation at Yale.

The chemotherapy of disseminated melanoma is limited. The most thoroughly tested active agent is DTIC (5-) (3-3-dimethyl-1-triazeno imidazole 4-carboximide). It produces objective response with 50% or greater reduction in the product of perpendicular diameters of measurable disease in 16 to 31% of patients. The average response to DTIC lasts 5 to 7 months, and the patient most likely to respond is the previously untreated woman with disease limited to skin, lymph node, or soft tissue sites. Visceral disease of liver, brain, and bone are more refractory.[26] The nitrosoureas, including Methyl-CCNU (a lipid soluble, orally administered congener) appear somewhat less active, and have been utilized as second line agents. Unfortunately, despite penetration of the central nervous system, these agents have not exhibited any significant activity against occult or overt central nervous system disease. Patients failing DTIC have generally not exhibited significant response rates to Methyl-CCNU. Most other chemotherapeutic agents have exhibited only background levels of activity against melanoma, even in a vast number of combinations and permutations. More recent suggestions of significant response rates to dibromodulcitol in patients refractory to DTIC and nitrosoureas offer prospects of more effective combination therapy with this new Phase II agent.[27]

The immunotherapy of advanced malignant melanoma has been pursued on the strength of findings that general immunological depression has been correlated with stage of disease in a number of malignant disorders,[28] and on the presumption that spontaneous regression observed in malignant melanoma is immunologically mediated.[29] Nonspecific immunostimulants such as Bacillus Calmette-Guerin (BCG) and the methanol extractable residue of BCG (MER), have been assessed in a number of clinical trials to date. Clearly these agents, as well as topical contact sensitizing agents, when given intralesionally, may cause significant or total regression of individual cutaneous metastases. Regression of some distant uninjected lesions has been observed in 15 to 20% of patients treated in this fashion. Intralesional injection can minimize local cutaneous disease, but probably does not prolong survival.[30] Intralesional BCG is notably associated with a significant frequency of complications.[31] Administration of BCG by inoculation intradermally by tine or by scoring of the skin (scarification) has avoided many of the complications of intralesional therapy, and has been reported to yield improved response with DTIC employed against metastatic melanoma.[32] The value of such therapy has been most apparent in palliative management, and awaits more rigorous randomized prospective trials before conclusions about survival advantage in treated groups may be established.

The lack of therapeutic impact on survival, and the lack of highly active drug therapy programs for advanced melanoma have stimulated research in two directions. It has fostered the development of a variety of new phase I and phase II programs, and has also led to the application of existing programs at earlier stages of melanoma, when tumor burden is presumed to be smaller and more susceptible to therapeutic effects. One of the most intriguing agents under phase II investigation is interferon, a glycoprotein lymphokine with antiviral and antitumor activity in experimental systems. While preliminary experimental studies indicate that this agent may have cytostatic effect on melanoma in the mouse, and may be significantly active against certain hematologic and mammary malignancies in man, it will not probably meet early public expectations as a general panacea for cancer. Supplies of interferon produced from fibroblasts (F), leukocytes (Le), or lymphoblasts each have theoretical and practical limitations. For the present, constraints of supply and cost have led the American Cancer Society to purchase a sufficient amount of interferon to permit a multi-institutional investigation of melanoma, myeloma, breast cancer, and lymphoma. The interferon melanoma trial will be carried out in part at Yale-New Haven Hospital, Memorial Sloan-Kettering, U.C.L.A., and M.D. Anderson Hospitals. Only patients with disease limited to skin, lymph nodes, soft tissues, and minor involvement of the lung will be eligible for trial, which will require intensive studies and hospitalization for a period of up to two weeks for initiation of therapy, and a week for restudy after 6 weeks of treatment.

The difficulty of treating established metastatic recurrent melanoma has fostered many surgical adjuvant efforts to eliminate occult "micro" metastatic disease which is the precursor of gross recurrence. Early data suggests that post-operative treatment with DTIC and BCG may improve the prognosis of patients with high risk Clark Level III, IV, or V, clinical Stage I melanomas of thickness greater than 1.5 mm or Stage II disease.[33] One unconfirmed prospective randomized study currently at twenty-five months median follow-up suggests that recurrence has been limited to 10% of patients receiving DTIC plus BCG, compared to relapse rates of 45% in patients receiving DTIC alone, and 27% in patients receiving BCG alone. Problems with this study include the absence of a control group receiving neither BCG nor DTIC, and a relative disproportion of surgical Stage II patients, and males, in the inferior DTIC-only arm. It is hoped that these preliminary results will be corroborated, and that such approaches will have a major impact on the morbidity and the mortality of operable melanoma. Other large studies have failed to suggest a benefit of BCG alone as adjuvant therapy, and it is clear that more studies will be required to answer the question.

Current studies ongoing at Yale include an adjuvant trial of BCG plus DTIC in doses which have been reported to be most active as adjuvant therapy,[33] in comparison to a program of depigmentation therapy with the topical agent monobenzyl ether of hydroquinone. The rationale for this program of depigmentation as a therapeutic modality against melanoma lies in the long standing observation that spontaneous depigmentation (vitiligo, halo nevi, and halo metastases or halo primaries) has been observed with increased frequency (20-30%) in melanoma patients we have followed for a period of time.[35] [36] Vitiligo is known to be associated with autoimmune destruction of melanocytes in certain circumstances,[37] and melanocytes are the progenitors of the malignant cell in melanoma. Thus, it may be possible that the induction of depigmentation and autoimmunization against normal melanocytes is protective against melanoma and accounts for the observation of vitiligo in patients with spontaneous regression of melanoma, or prolonged survival of advanced metastatic disease. This is prospectively being investigated in conjunction with detailed immunological studies of humoral and cellular responses to autologous melanoma, as well as histological evaluation of the course of cutaneous nevi and normal pigment cells in patients under study at the multidisciplinary Melanoma Clinic at Yale.

Surgical adjuvant studies at Yale have focused upon the preoperative intralymphatic, and local intraoperative instillation of MER, to optimize regional immunological stimulation of patients undergoing primary surgery. These are also prospectively being monitored by tests of cellular immune functions against melanoma *in vitro*, in hopes that such prospective monitoring of therapeutic modalities will allow them to be modulated and improved at the most rapid pace possible.

The dermatological involvement in multidisciplinary treatments of melanoma is diverse as well, and has led to recent appreciation of an association between melanoma and increased numbers of cutaneous nevi or lentigines in certain patients as well as their relatives. Indeed, the increased risk of melanoma in patients who are cured of their first melanoma argues for close dermatologic surveillance in all patients with melanoma. We are hopeful that the prospective study of nevi in patients with melanoma, as well as in patients without melanoma who experience change in cutaneous nevi associated with the use of hormones, such as contraceptives—or even pregnancy—may allow more definitive statements to be made about the relationship between endocrine involvement and melanoma.

Finally, a multidisciplinary approach to melanoma, in which dermatologists, medical oncologists, plastic surgeons, and specialized nurses jointly follow patients should offer the greatest chance to optimize care of the melanoma patient as well as advancing our basic and clinical knowledge of pigment cell neoplasia.

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Three Hundred Years of Parenteral Nutrition: The History of Intravenous Nutritional Therapy

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ABSTRACT—Intravenous administration of "hyperalimentation" solutions has probably been one of the most significant advances to the field of medicine in the past 15 years. The fascinating history from Sir Christopher Wren in 1656 to Dr. Stanley Dudrick's work is traced with the significant advances and modifications that have recently occurred. Prospects for the future are also elaborated.

Ever since Sir Christopher Wren, used a goose quill attached to a pig's bladder to administer wine, ale and morphine intravenously to a dog, in 1656, man has searched to provide nutrition to sick patients who were unable to utilize the gastrointestinal tract.[1] [2] Not until 1966 did Dr. Stanley Dudrick utilize previously known techniques of central vein catheterization and intravenous protein hydrolysates to prove that intravenous hyperalimentation can be a safe, effective and often life-saving form of nutrition.[3] His technique is thought by many to be the greatest advance to the surgical patient in the past 15 years.

Sir Christopher Wren was probably the first individual to administer any medication intravenously.[1] [2] He was also the architect of St. Paul's Cathedral in London. Less than 30 years earlier, William Harvey discovered the circulation of blood. In 1662, Richard Lower of Oxford reported experiments with blood transfusions and intravenous injections in animals. Very soon thereafter, in 1667, Jean Baptiste Denis, physician to Louis XIV, performed the first documented blood transfusion from a lamb to a human being.[4] Several years later (1670), *Clymatica Nova* was printed in Holland, illustrating the flow of venous blood, as well as the technique of intravenous infusion in the arm and leg of man. Blood transfusion from animal-to-animal as well as man-to-man was demonstrated. Little was known at that time about blood typing and cross-matching, the effects of pyrogens, or hypotonic solutes on the red blood cell. Until the basic concepts of microbiology were described by Pasteur and the subsequent application of aesepsis by Lister, it was understandable that little progress was made until 200 years later. Claude Bernard, the noted physiologist, was the first to infuse dextrose solutions into animals, in 1843.[4] Some fifty years later, Biedl and Kraus attempted infusion of these same dextrose solutions into humans.[5] Several years earlier, Rudolph Matas of New Orleans, in 1891, reported the treatment of shock in man with intravenous saline.[6]

Intravenous Protein Hydrolysates

The fact that proteins could be hydrolyzed into amino acids was known in the late 1800's. Credit for synthesis of polypeptides from amino acid residues is given to the German biochemist, Emil Fischer, in the early 1900's; however, allergic reactions of foreign proteins was well known by this time and the intravenous route was unsuccessful.[7] Early attempts of non-oral administration was via protoclysis infusion into the rectum. Whole protein with eggs and milk as the basic ingredients was given by this route until Edsall and Miller analyzed the returning stool and demonstrated almost no absorption of nutrients. In 1909, Folin showed that some amino acids could be absorbed from isolated large bowel loops in a cat.[7] [8]

Henriques and Anderson were truly the first to intravenously administer protein hydrolysates in 1913.[9] The hydrolysates were made from the digestion of goat muscle with intestinal mucosa and pancreatin. A goat was infused for 16 consecutive days and nitrogen balance was claimed, but not until 23 years later was Dr. Robert Elman of St. Louis able to give protein hydrolysates intravenously to man.[10] [11] The solution was prepared as an enzymatic hydrolysate of casein and pancreas. The solution manufactured by Mead-Johnson of Indiana, originally was sold under the trade name of Amigen®. Later, a variety of

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hydrolyzed proteins of casein alone and, still later, of fibrin were manufactured by the Abbott Company under the name Aminosol®.[12] Several years after that, the Merck Company produced a solution of entirely pure amino acids. The work of Elman achieved positive nitrogen balance in post-operative patients measured by both the Kjeldahl and nesslerization methods.[10] [11] This was really the impetus needed to give hyperalimentation its present day notoriety. He encountered many problems, though. First, the amount of fluid which a sick patient could handle safely was limited to 35-50 cc/kg, or 3-3.5 liters per day, and this often required using diuretics such as chlorothiazide, mannitol, or ethacrynic acid to promote excretion.[14] This never became popular because of the risk of fluid overload. Secondly, the caloric density of the infusion was limited. Protein and carbohydrates yield only 4 Cal/Gm. Caloric requirements of sick patients approached 4000-5000 Calories per day. Hydrolysates, which contain only 50% free amino acids, yield only 2-3 Cal/Gm. Later it was discovered that the polypeptide byproducts of hydrolysates were excreted essentially unchanged in the urine and produced no significant nutritional value. This had led to the present day popularization of crystalline amino acids rather than hydrolysates in hyperalimentation solutions, Attempts at increasing caloric density were made by infusing alcohol (7Cal/Gm) or fat (9 Cal/Gm).[15] Intravenous fat will be discussed later, but the obvious inebriation of patients receiving alcohol limited its use. The third problem encountered was that of solution concentration. When an attempt was made to increase the concentration of dextrose above 5% or 10%, phlebitis or thrombosis of peripheral veins resulted. Early attempts at central venous infusion were made via the inferior vena cava in dying patients, but autopsies showed clot formation along the catheter.[16] This technique was quickly abandoned.

After considerable experimentation, in 1966, Dudrick and Vars reported positive nitrogen balance and weight gain in purebred beagle puppies that were fed through a plastic catheter extending to the superior vena cava via the jugular vein.[3] At 12 weeks of age, the puppies were divided into two groups. Central catheters were inserted into one-half of the animals and hypertonic glucose, fibrin hydrolysate, vitamins and minerals were given as their only source of nutrition. The size-matched litter mates were fed orally a diet nutritionally similar to that infused in the other group. Both groups of animals initially doubled their weight and growth, then tripled it, and in a nine to twelve-month period achieved adult stature. In 1968, Dudrick, Wilmore and Vars published reports of this technique in adult patients, also achieving positive nitrogen balance, weight gain, improved wound healing and closure of intestinal fistulae.[17] [18] Thus, the era of total parenteral nutrition had begun.

Credit for popularization of this great clinical achievement has and will always go to Dr. Stanley Dudrick. However, as expected, skepticism prevailed initially. Protein hydrolysates were well known to clinicians as a source of amino acids—as was dextrose. In addition, the clinical application of the percutaneous cannulation of the superior vena cava via the subclavian vein was first described in French by Aubaniac in 1952.[19] By 1962, Wilson popularized the technique for monitoring central venous pressures.[20] The medical community feared that prolonged infusion of hypertonic glucose solutions, that were known culture media themselves, through a cannula resting several inches from the heart would invariably result in fatal sepsis. Attempts were made to infuse solutions through peripheral high flow arteriovenous shunts, but the subclavian route prevailed.[21] Significant complications did occur, but as clinicians became aware of the techniques of catheter maintenance and sterile mixing of solutions, benefits of hyperalimentation began to outweigh the risks. Safe, long-term CVP catherization could be maintained.[22] Intravenous hyperalimentation, ironically, became the mainstay of treatment of many severely septic patients.

In the early 1970's, Scribner, et al., applying home care techniques perfected for renal dialysis, trained patients with massive bowel resections to mix solutions, clean the catheter, and receive TPN at home.[23] [24] Presently, over 150 patients around the country are maintained, at home, on intravenous hyperalimentation. Many of these patients have traveled extensively without problems.

Most recently, a solution of the L-form of the nine essential amino acids became available for use in renal failure patients. In 1969, Wilmore and Dudrick applied the principles of nutrition in anuric patients, first published by Giordano and Giovanetti in 1963; that is, providing a diet high in essential amino acids.[25] [26] The increased levels of urea could be broken down into ammonia by the intestinal bacteria and then transported to the liver by the enterohepatic circulation whereby all the non-essential amino acids could be produced.[27] [28] Abel in 1972 demonstrated increased survival in acute renal failure patients routinely hyperalimented in this fashion.[29] [30] [31]

Exciting work with liver failure patients has also been reported over the last several years.[32] Work by Fisher in identifying plasma amino acid abnormalities in patients with alcoholic encephalopathy has received much attention. A decrease in branched-chain amino acids, leucine, isoleucine, and valine, with a concomitant elevation of aromatic amino acids, phenylalanine and tyrosine, had been documented. "Laundering" this abnormal pattern in comatose patients with specially formulated crystalline amino acid solutions (i.e. high in branch chain and low in aromatic amino acids) had led to a reversal of the abnormality, as well as clinical improvement in the level of consciousness. Unfortunately, hepatic encephalopathy from other causes is associated with an increase in many of the plasma amino acids and may someday be treated by dialysis.[33] Previously, hyperalimentation with hydrolysates in this group of patients has led to deterioration of mental status—presumably from the high ammonia load present. Crystalline amino acids made from the chloride and acetate salts are available and are relatively free of ammonia.

Intravenous Fat Solution

Intravenous fat for parenteral nutrition has paralleled the developments of hydrolysates and amino acids. The high caloric density of 9 Cal/Gm was recognized for years. Several investigators attempted to give all nutrients, including fat, subcutaneously in the late 1800's and early 1900's. In 1896, Mensel and Perco first published reports of this technique.[34] Whittaker in 1876, Pick in 1879, Eichhorn in 1881, and Friedrich in 1904 all described subcutaneous injection of milk with egg yolk or cod liver oil.[35] [36] Leube in 1895 described subcutaneous injections of camphor oil in patients with cardiac failure.[35] The first fat emulsion given intravenously to animals was by Murlin and Riche in 1915.[37] Credit, however, goes to Yamakawa of Japan, in 1920, for first administering fat emulsions in pediatric patients in the United States.[7] Extensive studies in this country, Europe and Sweden were done to perfect the emulsifying agent-consistently the problem with intravenous fat solutions.

Both cotton seed emulsions (Lipomul® and Infonutrol®) were commercially available in the United States by the early 1950's. Evidence for their biologic utilization was conclusive; however, problems with febrile reactions, rashes, and liver function abnormalities were evident. An overloading syndrome was also observed during long-term administration. Even limited amounts—500cc of a 15% solution providing only 675 Cal.—caused adverse reactions. Finally, the Food and Drug Administration limited use of fat emulsions so severely that production in the U.S. was stopped by 1964.[34] [39]

As long-term standard hyperalimentation results began to accumulate, essential fatty acid deficiency became evident in both adult and pediatric patients. As more and more experience was gained, fat was discovered to be an essential nutrient to man. Work in Europe and Sweden led to the development of the soybean oil emulsion, (Intralipid®); however, the past experience of fat emulsion in this country led the Food and Drug Administration to delay approval until 1976.

At the present time, only (Intralipid®), a 10% soybean oil extract, emulsified by purified egg phospholipids in glycerol and water is available in this country. The clear advantage of this preparation to standard hyperalimentation solutions appears to be its osmolality allowing peripheral administration. Despite initial enthusiasm for the product, significant restrictions on the total and percent fat intake, volume and cost have limited its usefulness. Nevertheless, the agent is still a well-tolerated, safe addition to the surgeon's armamentarium.

With greater utilization of TPN for long periods, trace element deficiencies became evident. Frequent blood transfusion was the routine source of essential elements such as Cu, Zn, Mg, Mn, etc.; however, prolonged parenteral use outstripped replacement by transfusion. Several pharmaceutical companies are now producing a ready-made formula of trace elements for use in prolonged TPN.

Peripheral Amino Acids

The most recent frontier to be challenged in intravenous nutrition is the "old standard"—5% dextrose. Historically, Biedl and Kraus first attempted infusion of dextrose in humans, but credit for its widespread use goes to Dr. James Gamble, then a Harvard professor of pediatrics and expert on nutrition. He was commissioned by the military in World War II to find the optimal physiologic solution for life raft rations.[42] He noted that dextrose was salt and protein sparing while providing some energy, however small. Ketosis was also averted. Five percent dextrose was used universally until 1973, when Blackburn and Flatt proposed the peripheral infusion if isotonic crystalline amino acids *alone*, rather than dextrose containing solutions.[43] Their results indicated that pure amino acids alone would keep insulin and glucose levels depressed and increase free fatty acid mobilization, thus sparing body protein, as in a weight reduction diet. In the initial studies, ketosis was felt to be the important factor mediating the protein sparing effect and appeared to be a function of the infused amino acids alone and *not* related to the degree of ketosis or endogenous fat mobilization.[44] Opponents of this technique have cited the added expense just to create *less* negative nitrogen balance while *not achieving positive* balance as with hyperalimentation. No study has convincingly documented augmented wound healing or shorter hospitalization with this technique to justify routine use at this time. Obviously more research in this area will be forthcoming. Routine use of peripheral amino acids in post-operative surgical patients may someday be commonplace.

Thus, the past three hundred years has enlightened modern medicine to advances in intravenous nutrition never dreamed possible before. One cannot help but feel that advances in the next three hundred years will produce astounding discoveries of equal magnitude.

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Police Testing and Informed Consent

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A perennial question asked us by hospitals, physicians, the police and prosecutors is under what circumstances the police in Connecticut may order a physician to take a blood sample, or perform a test, when a patient refuses to or is incapable of granting informed consent.

Our response, in summary, is that if an individual refuses to or is incapable of signing a consent form or otherwise giving informed consent, blood should not be drawn nor should tests be performed solely at the request or order of the police or prosecutor.

Recently, several prosecutors and a representative of the state police have expressed the opinion that a physician is required to obey a request or order of the police, whether or not the individual consents, on the theory that drawing blood is a legitimate search and seizure if incident to a lawful arrest. As authority for this position, they cite the United States Supreme Court case of *Schmerber* v. *California,* 383 U.S. 757 (1966), and the language in Section 14-227c of the Connecticut General Statutes which provides that, in the event of a fatal accident, "[t]o the extent provided by law, a blood or breath sample may . . . be obtained from any surviving operator whose motor vehicle is involved in such an accident." Their argument is that the *Schmerber* case sanctions the forcible withdrawal of blood, and therefore provides the legal authority which permits the police to order blood drawn under the quoted language in Section 14-227c.

While we are sympathetic to the problem confronting the police when an obviously intoxicated driver refuses to consent to a test and the blood alcohol or drug level then begins to decline, we feel that neither *Schmerber* nor Section 14-227c supports the position being advanced, and that relief, if any, must come from the General Assembly.

Federal Law

In *Schmerber,* a doctor was ordered by the police to take a blood sample despite the patient's refusal to give *the police* his consent; the issue of whether *the physician* was required to obtain informed consent from the patient was never raised. The Supreme Court, by a vote of 5-4, held that because an emergency had existed (namely, the blood alcohol level would have diminished if a test were not immediately performed), the police officer was not required to obtain a search warrant. Accordingly, the evidence obtained was an appropriate seizure incident to the driver's lawful arrest and was therefore admissible at his trial. 384 U.S. at 770-71. It is important to remember, however, that the Court did not have before it the questions of (1) whether the physician was required to obey the policeman's order, (2) whether the fact that the police could lawfully seize the blood sample obviated the need for the physician to obtain the patient's informed consent, or (3) whether the physician would be liable for damages in a civil action if he complied with the police order without first obtaining the patient's consent.

The only other United States Supreme Court case in which the issue of blood-alcohol testing has been considered in this context is *Breithaupt* v. *Abram,* 352 U.S. 432 (1957). In *Breithaupt,* which antedates *Schmerber* by about a decade, the Court held similarly that the taking of blood, at the direction of the police, from an unconscious patient after an automobile accident, did not violate the constitutional right to a fair trial. As in *Schmerber,* the only issue before the Court was the admissibility of the test results.

Another Supreme Court case, *Rochin* v. *California,* 342 U.S. 165 (1952), should be mentioned here. In

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that case, a physician, at the request of the police, forcibly pumped a patient's stomach to obtain evidence (swallowed pills). Justice Frankfurter, speaking for the majority, held that the conduct in question, which had been found by the trial court to constitute assault and battery, torture, and false imprisonment, so shocked the conscience of the Supreme Court that it thereby violated the requirements of the due process clause of the Constitution; therefore the pills were not admissible and the patient's conviction and sixty day sentence for possession of morphine was reversed. It should be noted that in *Breithaupt* the Court had emphasized that the test performed on the driver was not in the least offensive, but "[t]his is not to say that the indiscriminate taking of blood under different conditions or by those not competent to do so may not amount to such 'brutality' as would come under the Rochin rule." 352 U.S. at 437-38. Once again, the Court, in deciding *Rochin,* was concerned only with the admissibility of the evidence obtained from the search in question. It did not address itself to the propriety of the physician's conduct, nor did it consider the question of potential civil liability based on the trial court's findings.

We think it clear that these cases lend absolutely no support to the argument that the police may order a physician to take blood when the physician has not obtained the patient's consent. The cases are concerned solely with the legality of the particular searches at issue and with the admissibility of the evidence obtained. Justice Heffernan of the Wisconsin Supreme Court viewed these cases exactly this way in his opinion in *Waukesha Memorial Hospital, Inc.* v. *Baird,* 173 N.W.2d 700 (Wis. 1970). *Schmerber,* he concluded, merely decided that the blood so withdrawn did not constitute incriminating testimonial evidence obtained in violation of the Constitution. (*Waukesha* was an action for declaratory judgment by physicians who claimed that the police had threatened them with prosecution if they refused to take blood without a patient's consent. The doctors sought a declaratory judgment as to whether the police could order them to take the blood, and as to their civil liability if they complied with a police order against a patient's wishes. The Wisconsin court said that the case was speculative as presented, and that therefore the issue should not be decided until a real case or controversy arose. The court noted, however, that it was not up to the police to threaten a prosecution.)

Connecticut Law

There is nothing in Connecticut law, moreover, which would support the position that the police can order a physician to administer a test without patient consent. Section 14-227c of the Connecticut General Statutes, referred to above, provides as follows:

> As part of the investigation of any motor vehicle accident resulting in a fatality, the chief medical examiner, an associate medical examiner, a pathologist as specified in section 19-529, an authorized assistant medical examiner, or a coroner, as the case may be, shall order that a blood sample be taken from the body of any operator or pedestrian who dies as a result of such accident. Such blood samples shall be examined for the presence and concentration of alcohol by the toxicological laboratory of the department of health services by the office of the chief medical examiner. *To the extent provided by law, a blood or breath sample may also be obtained from any surviving operator* whose motor vehicle is involved in such an accident. The blood samples obtained from the surviving operator shall be examined for the presence and concentration of alcohol by the toxicological laboratory of the department of health services. Nothing in this section or section 19-530 shall be construed as requiring such medical examiner to perform an autopsy in connection with obtaining such blood samples. (Emphasis added.)

The proponents of testing without consent argue that the phrase in Section 14-227c, "to the extent provided by law," authorizes the police to order a test without consent for the reasons set forth in *Schmerber,* and, presumably, *Breithaupt.* As we indicated above, however, these cases provide no such authority, but merely hold that if the police perform the test, they have not violated the individual's constitutional right to be free from unreasonable searches and seizures. The only Connecticut case we know of which has interpreted this phrase in the context with which we are concerned is *State* v. *Robarge,* 35 Conn. Supp. 511, 391 A.2d 184 (Super. Ct. App. Sess. 1977). In *Robarge,* Judge Shea, in an opinion concurred in by Judges Healey and Parskey, read the phrase "to the extent provided by law," as authorizing only a medical examiner or coroner to take a sample from the surviving driver.

Moreover, Section 14-227b of the General Statutes specifies that if a person who has been placed under arrest for operating a motor vehicle while under the influence of alcohol or drugs refuses to submit to a test, the test shall not be given; and Section 14-227a(b) provides that, in any criminal prosecution for operation of a motor vehicle while under the influence of alcohol or drugs, evidence with respect to the amount of alcohol or drugs in the defendant's blood at the time of the offense, as shown by chemical analysis, shall only be admissible if the defendant consented to the tests. As for ordering tests prior to arrest, we know of nothing in the Connecticut General Statutes or case law which would justify such action in the absence of the operator's informed consent to *both* the police and the physician. *See*

State v. *Singleton,* 174 Conn. 112, 115-16, 384 A.2d 334 (1977).

In summary, we find no Connecticut case law or statute which authorizes a private physician to take a blood sample on the request or order of the police without the consent of the person who is to be tested.

Implied Consent

Section 14-227b of the Connecticut General Statutes[1] does, however, provide a mandatory penalty for refusing to consent to a test. Thus, if it is found by the court or jury that there was probable cause for the arrest, that the refusal was knowing and wilful, and that the person was in fact operating a motor vehicle, then, "the commissioner of motor vehicles shall suspend or revoke his license or nonresident operating privilege."

As it has been construed, the function of the first sentence (implied consent) is to put motorists on notice that consent to a test is a condition of driving on the roads of the state. Although the state cannot actually force a person to consent to a test, if an arrest is made and the driver refuses to consent, the individual's license will be suspended or revoked for failure to comply with the condition imposed by statute.

A 1965 Connecticut Superior Court decision, *State* v. *Towry,* 26 Conn. Supp. 35, 210 A.2d 455, is almost directly on point. In that case, an individual had been found unconscious behind the wheel of a motor vehicle. He was taken by ambulance to a hospital, and a sample of blood was taken by the medical examiner without his consent and without a search warrant. The individual subsequently was arrested based on the results of the blood test. At trial, the defendant urged that the results should be suppressed because he had not consented to the test and because the test was not incident to a lawful arrest. The State argued in part that the taking of the defendant's blood was expressly authorized by the "implied consent" provisions of Section 14-227b. The court found that the statute does *not* authorize a test in the absence of actual consent, and Judge Thim's analysis of the issue is worth quoting at length:

"Sections 14-227a and 14-227b were enacted in 1963 as part of Public Act No. 616, entitled 'An Act Concerning Implied Consent to Tests for Intoxication.' Both sections are interrelated and they give rise to two separate and distinct proceedings, one dealing with criminal procedure and the other dealing with revocation of license. Section 14-227a declares it a crime to operate a motor vehicle while under the influence of intoxicating liquor and prescribes a procedure to follow for the admission into evidence of the results of a chemical test of a defendant's blood or breath taken with his consent. Section 14-227b requires the motor vehicle commissioner to suspend or revoke an operator's driving license when the operator refuses upon request to submit to a blood or breath test.

"Before the results of a chemical test can be admitted in evidence under the provisions of §14-227a, the state must prove that the defendant consented to the taking of the test. The license revocation of §14-227b only becomes operative in the event the defendant has refused to consent to the test under the conditions set forth in §14-227a. *A condition imposed on an operator of a motor vehicle placed under arrest for driving while under the influence of liquor is that he consent to a chemical test under the provision of §14-227a. His refusal to take the test results in a mandatory suspension or revocation of his license.*

"The implied consent provision of §14-227b does not authorize the taking of blood from the defendant, who was unconscious at the time of the taking. At no time did he consent or refuse to submit to a chemical test. Another important element, not present in this case, is the fact that the defendant was not under arrest at the time the blood sample was taken from him. It is true that §14-227a does not contain a specific requirement of the operator's arrest prior to the request to submit to a blood test. However, in construing both sections, the conclusion is reached that the act requires the defendant to be placed under arrest before the request to give a sample of blood can be made under §14-227a. To interpret §14-227a so that a police officer is authorized to request an operator to furnish a sample of blood before his arrest may well result in an attack being made on the constitutional validity of the section. See *Matter of Schutt* v. *Macduff,* 205 Misc. 43, 54; LaPlante, 'Alcohol Testing,' 38 Conn. B.J. 16, 21, 39, id. 72." *State* v. *Towry,* 26 Conn. Supp. 35, 40-41, 210 A.2d 455 (1965). (Emphasis added.)

Significantly, in the *Towry* case blood was drawn by the *medical examiner,* not by a member of the hospital staff, so the issue of informed consent to the physician—as opposed to the police—was not even present in the case. Nevertheless, the case clearly stands for the proposition that there must be *actual consent* before a test can be given. *See also* LaPlante, Alcohol Testing: Connecticut's Implied Consent Statute, 38 Conn. B.J. 16, 26-27 (1964), wherein Professor LaPlante concludes that an actual request and an actual consent are called for under the statute.

Recently, in *Mackey* v. *Montrym,* ________ U.S. ________ , 99 S. Ct. 2612 (June 25, 1979), the United States Supreme Court held that a similar Massachusetts statute, which provides that a driver's license may be suspended because of the licensee's refusal to take a breathalyzer test upon arrest for driving while under the influence of intoxicating liquor, does not violate the Constitution's Due Process Clause. The statute provided that if the driver refused to consent, after having been informed that such refusal would result in a ninety-day suspension of the individual's driver's license, "no such test or analysis shall be made." The Court noted that the state "must have the authority, if it is to protect people from drunk drivers, to require that a breathalyzer test record the alcoholic content of the bloodstream at the earliest possible moment." 99 S. Ct. at 2619. It should be emphasized, however, that nothing in the Massachusetts statute or in the Supreme Court's opinion in any way supports the view that a state may *compel* a driver to take any test. The Court merely upheld the right of the state to "summarily [remove] from the road those who refuse to take the test. A state plainly has the right to offer incentives for taking a test that provides the most reliable form of evidence of intoxication for use in subsequent proceedings." *Id.* at 2621. Significantly, four of the nine members of the Court dissented. They would have required a formal hearing prior to the suspension.

As noted, under the Connecticut statute a person need not consent to a test, but if consent is withheld, the privilege of driving on the highways of the state will be rescinded. "The whole philosophy behind §14-227b—its raison d'etre, one might say—is to provide some way of reaching out against an accused, though not as part of the criminal law, to prevent the obstruction of a fixed legislative policy. This reaching out, so to speak, is merely directed toward the suspension or revocation of the operating privileges of the accused." *State* v. *Hanusiak,* 4 Conn. Cir. 34, 39, 225 A.2d 208 (1966) (dissenting opinion).

A substantial number of states now have implied consent statutes. Many of these are similar to the Connecticut statute, but some explicitly provide that blood samples may be taken from persons incapable of refusing a test by reason of unconsciousness or other mental or physical condition. Court decisions under the law of other states have held in substance that explicit consent is not required, and that implied consent will justify withdrawing blood from an individual incapable of refusing a test. On the other hand, many state courts have held that express consent is required. These cases are collected in an annotation entitled "Admissibility in Criminal Case of Blood Alcohol Test Where Blood Was Taken From Unconscious Driver," 72 A.L.R.3d 325 (1976). It should be emphasized, however, that even in those cases which held that implied consent is sufficient in the absence of an express refusal, the consent at issue was consent to the *state, i.e.,* the police. There is nothing in any of the cases which indicates that consent to the state also covers consent to the physician. Indeed, there is a paragraph in the annotation which focuses, at least to some extent, on this problem:

"It should also be noted that it is sometimes difficult to convince physicians to co-operate in administering chemical tests in view of the fact that insurance policies covering malpractice typically protect the physician only when the doctor-patient relationship has been established. Because the request to take a blood sample ordinarily comes from a police officer and not the defendant, the physician-patient relationship may never exist in such a situation."
Note, 72 A.L.R.3d 325, 333.

Even where a physician-patient relationship does exist,[2] taking blood without consent may constitute a wilful tort—assault and battery—and thus may not be covered under the physician's professional liability insurance policy.[3] Moreover, if a blood sample is taken for the police without the informed consent of the driver-patient, the physician could be liable for whatever damage ensues whether or not there was malpractice. For example, if the patient develops an infection, or is harmed through blood loss (because he takes anticoagulants or is a hemophiliac), the physician will be responsible. Furthermore, if a physician assists the police in restraining a patient, and the patient is injured in the struggle, the physician also could end up as a defendant in a civil action for damages arising from the restraint.

In sum, as it has been construed and interpreted, there is nothing in the *Connecticut* implied consent statute which would justify the conclusion that consent is unnecessary in the absence of a refusal. On the contrary, it is our view that under the Connecticut statute both the police *and* the physician must obtain actual informed consent before blood may be withdrawn.

Capacity to Consent

On the question of whether an intoxicated person ever can give informed consent, we believe that a particular individual's capacity to consent would be a matter within the discretion of the attending physician. In one case arising under the implied consent statute, for example, the court was faced with the issue of whether a person under a conservatorship was capable of giving informed consent. The court stated that consent must be freely and voluntarily given, under conditions where the individual is mentally and physically able to make a choice. However, the court continued, if a person is mentally capable of perceiving or understanding events and surroundings, he or she is legally capable of giving consent. On this basis, the court concluded that "the fact that the defendant was under a conservatorship did not *in and of itself* prevent the defendant from giving a valid consent." *State* v. *Tarcha,* 3 Conn. Cir. 43, 47, 207 A.2d 72 (1964) (emphasis added).

In his article in the Connecticut Bar Journal (38 Conn. B.J. 16, 24-25), Professor LaPlante also dealt with the problem of capacity to consent under the implied consent statute. He pointed out that "a person may be sufficiently intoxicated so as to be guilty of driving while under the influence of liquor and yet not be so intoxicated as to render him incapable of giving his consent to the test." In support of this position, he quoted the following language from a Texas court opinion:

"[A] person under the influence of intoxicating liquor, as defined by the penal code, need not be so intoxicated as to be incapable of entering into a valid agreement, and yet be sufficiently intoxicated to come within the statute . . . defining driving on a public highway while intoxicated."

Jones v. *State*, 159 Tex. Crim. 29, 261 S.W. 2d 161, 162, *cert. denied*, 346 U.S. 830 (1953).

We point out that these cases were dealing with the question of informed consent in the context of a *criminal* proceeding. The standard for informed consent to a medical procedure in the context of a civil action may differ. Thus, it is up to the *physician*, not the police, to determine whether an intoxicated person is capable of giving a physician informed consent to perform a medical procedure.

Finally, it should be kept in mind that the patient must know the purpose of the test in order for the consent to be "informed." *Cf. Graves* v. *Beto*, 424 F.2d 524 (5th Cir.), *cert. denied*, 400 U.S. 960 (1970) (A rape defendant's consent to a blood test was not freely and intelligently given where acquiescence to the test was obtained by intimating to the defendant that the test was being performed simply to determine whether he should be detained on a charge of public drunkenness.) (Wisdom, J.).

Conclusion

Based on all of the foregoing, it is our conclusion that tests should not be performed at the request of the police or prosecutor unless the physician has obtained the consent of the person who is to be tested. Furthermore, the individual's condition must be such that, in the physician's opinion, he or she is capable of giving an informed consent. In the absence of consent, tests should be performed by the medical examiner or coroner rather than by hospital personnel. We emphasize that medically necessary tests may be performed by hospital personnel even if the individual is not capable of granting consent, on the theory that an emergency obviates the need for consent. However, the results of such medically indicated emergency tests should not subsequently be turned over to the police without either the authorization of the individual who was tested or a proper subpoena, search warrant, or other court order.[4]

REFERENCES

1. Any person who operates a motor vehicle in this state shall be deemed to have given his consent to a chemical analysis of his blood, breath or urine, and if said person is a minor, his parent or parents or guardian shall also be deemed to have given his consent. If any such person, having been placed under arrest for operating a motor vehicle under the influence of intoxicating liquor or any drug or both, and thereafter, after being apprised of his constitutional rights and having been requested to submit to a blood, breath or urine test at his option, refuses to submit to any of such tests, the test shall not be given. Upon the conclusion of the trial of such person on the charge of operating a motor vehicle under the influence of intoxicating liquor, or any drug or both, the court or jury to which such case was tried, upon request of the prosecuting attorney made immediately upon disposition of the case, shall make a finding concerning the following: (1) Whether or not there was probable cause for the arrest of such person; (2) whether or not the refusal to submit to the test was made knowingly and wilfully, and (3) whether such person was operating such motor vehicle. If the court or jury finds all of the foregoing in the affirmative, the commissioner of motor vehicles shall suspend or revoke his license or nonresident operating privilege, the terms and conditions of which shall be determined by said commissioner. The provisions of this section shall not apply to any person whose physical condition is such that, according to competent medical advice, such test would be inadvisable. The provisions of this section relative to suspension or revocation of a license or nonresident operating privilege shall not apply if the charge for which such person was arrested is nolled or changed. The state shall pay the reasonable charges of any physician who, at the request of a municipal police department, takes a blood sample for purposes of a test under the provisions of this section.
2. The question of whether or not an individual is in fact a "patient" is not relevant to the issue of informed consent in the context of this article. Such question, however, may be relevant to other unrelated matters, such as admissibility of evidence in court, or coverage under a professional liability insurance policy.
3. In December, 1976, the Attorney General of New York State issued an opinion to Dr. Whalen, New York's Commissioner of Health, who had inquired about the liability of a physician who takes a sample without consent but on the order of the police. New York has a statute, similar to Section 14-227b, which provides that if a patient refuses to submit to a chemical test it should not be performed. The statute also provides that a physician who performs a test at the request of the police may not be sued or held liable. The New York Attorney General was of the opinion that the taking of a motorist's blood after refusal would subject the physician to liability and he would not enjoy any statutory immunity. In Connecticut, of course, we do not have a statute which provides for immunity under any circumstances.
4. When a patient has been treated for drug or alcohol abuse, the question of the subsequent release of test results may be complicated. If the patient has been treated for drug or alcohol abuse, the record is subject to the provisions of the HEW confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2. These define the "record" as including any information relating to the patient. "Patient" is defined broadly and includes any individual "Who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug or alcohol abuse preliminary to a determination as to eligibility to participate in a treatment or rehabilitation program." They also require that a detailed consent-to-release form be signed by the patient. If the patient refuses to sign such an authorization, then, under the Regulations and the provisions of the Drug and Alcohol Abuse Acts, 21 U.S.C. § 1175, and 42 U.S.C. § 4582, the police must seek a court order. Before issuing any such order, the court first must determine that the need for disclosure is more in the public interest than the possible injury to the patient, the physician-patient relationship, and the treatment services. State law also poses a problem regarding drug abuse. Section 19-496c of the Connecticut General Statutes provides that if a person has requested treatment and rehabilitation for drug dependence, no hospital shall report or disclose the name of such person or the fact that treatment was requested or has been undertaken to any law enforcement officer or agency; and such information shall not be admissible as evidence in any court, grand jury or administrative proceeding unless authorized by the person seeking treatment.

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Steroid Receptors in Breast Cancer

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Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A Consensus Development Conference on Steroid Receptors in Breast Cancer was held at the National Institutes of Health June 27-29, 1979. The basic question asked at the meeting was:

Question: What is the value of steroid receptor assays to the clinical management of breast cancer?

At NIH, consensus development conferences bring together biomedical research scientists, practicing physicians, consumers, and others as appropriate in an effort to reach general agreement on the efficacy and safety of a medical technology. That technology may be a drug, device, or a medical or surgical procedure.

Following is the list of conclusions drawn by the NIH consensus development panel:

1. The original results from the 1974 NCI-sponsored meeting on estrogen receptors and human breast cancer, showing the utility of estrogen receptor assays in the management of advanced breast cancer patients, have been confirmed and are found to be strengthened significantly by the studies over the last 5 years. Clearly, few patients whose breast cancers lack cytosol estrogen receptor respond to endocrine therapies, while more than half of patients whose tumors contain estrogen receptors obtain objective remissions from such treatments. Thus, results of estrogen receptor assays provide valuable information for making the clinical decisions on the type of the therapy to be employed.

   For most early breast cancer patients sufficient primary tumor should be available for cytosol estrogen receptor assay. At time of recurrence, the metastatic lesions may be inaccessible or otherwise difficult to obtain. It is strongly recommended that each primary tumor be assayed for estrogen receptor so that the assay information will be available when needed at the time of disseminated disease. Current findings indicate that the cytosol estrogen receptor assay result on the primary tumor correlates well with response to endocrine therapy later, even though the time interval between assay and therapy may be more than several years.

2. It is evident that while almost all breast cancers which respond to endocrine therapy contain estrogen receptor, not all estrogen receptor containing breast cancers respond to endocrine therapy. To obtain additional confidence concerning the probability of patient response to endocrine therapy, one can determine actual quantitative amounts of estrogen receptor since it appears, in general, that patients with tumors containing

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NIH Consensus Development Conference Summary Vol. II.

EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

higher concentrations of cytosol estrogen receptor have an increased likelihood of response to endocrine therapy. Furthermore, knowledge of whether the tumor contains cytosol progestin receptor seems to add appreciably to the ability to predict whether the patient will respond to endocrine therapy.

3. At the present time, there does not appear to be any histopathologic feature which can predict the estrogen receptor status of the cancer, although more highly differentiated tumors (i.e., histologic grade 1) appear to have a higher proportion containing estrogen receptor than do the more poorly differentiated tumors.
4. There is no clear evidence that responses to chemotherapy correlate with the presence or absence of estrogen receptor. More basic laboratory and/or clinical studies are in order to understand how cancer cells are being affected by cytotoxic agents.
5. Stage II patients with tumors which lack estrogen receptors appear to recur earlier than those with estrogen receptor positive tumors, independent of the size of the tumor or nodal involvement. Regarding the length of survival or the prognosis for recurrence of Stage I patients, more data must be accumulated to determine whether the estrogen receptor status correlates in these cases.
6. The reliability of steroid receptor assays is paramount to their optional use for the clinical management of breast cancer. The obtaining of the proper tissue sample is of extreme importance and requires the cooperation of the surgeon, pathologist, and the assay laboratory. The following recommendations are made to the people performing steroid receptor assays:
   a. The tissue sample should be immediately chilled to ice temperature—and maintained at that temperature—and transported to the assay laboratory.
   b. A piece of the tissue sample directly adjacent to the piece for receptor assay should be sent to pathology for evaluation to insure that the sample to be assayed consists of tumor tissue.
   c. If the assay is not done on the same day, the tissue should be stored at -70° C or colder. Prolonged storage of tumor tissue prior to assay is to be discouraged.
   d. Currently, the most reliable and reproducible methods for cytosol estrogen receptor assay appear to be sucrose density gradient sedimentation analysis and multiple point dextran coated charcoal assay analyzed by Scatchard plot. As other methods appear, they should be validated against these methods.
   e. New techniques that localize receptor within tumor cells are desirable and may provide new or additional information. At the present time, no histochemical receptor assay can be considered validated and further work is needed to establish whether any such method has clinical usefulness.
7. There is a need for quality control of steroid receptor assays. In order to properly support the conduct of clinical trials in breast cancer, a quality control resource should be developed.

The consensus development conference was sponsored by the National Cancer Institute's Division of Cancer Biology and Diagnosis.

Members of the Consensus Development Panel were: Eugene R. DeSombre, M.D., University of Chicago, Chicago, Illinois, Chairman; Paul P. Carbone, M.D., Wisconsin Clinical Cancer Center, Madison, Wisconsin; Elwood V. Jensen, M.D., University of Chicago, Chicago, Illinois; Mortimer B. Lipsett, M.D., Clinical Center, National Institutes of Health, Bethesda, Maryland; William L McGuire, M.D., University of Texas School of Medicine, San Antonio, Texas; Samuel A. Wells, Jr., M.D., Duke University Medical Center, Durham, North Carolina; James L. Wittliff, M.D., University of Louisville, Louisville, Kentucky.

Summary of FTC's Opinion and Order

Report to the CSMS House of Delegates Semi-Annual Meeting, November 15, 1979

On October 24, 1979, the Federal Trade Commission issued its Final Order and Opinion in the proceeding against the Connecticut State Medical Society, New Haven County Medical Association, and American Medical Association. The FTC granted in part and denied in part the appeal of the Society and New Haven County, and denied in full the appeal of the AMA. In essence, the FTC affirmed the administrative law judge's findings of fact and conclusions of law as to all respondents (this is the denial in part of our appeal): the FTC found and concluded that all respondents are subject to the jurisdiction of the Commission; respondents acted in or affecting interstate commerce; each respondent had conspired with the other respondents, other medical societies, and respondents' members: and the conspiracy acted in violation of Section 5 of the Federal Trade Commission Act. The FTC issued a cease and desist order (not now in effect) against only the AMA (the deletion of CSMS and NHCMA from specifically being named is the granting in part of our appeal). The Opinion and Order are discussed below.

Jurisdiction. Section 4 of the Federal Trade Commission Act provides that the FTC has jurisdiction over a corporation only if it is "organized to carry on business for its own profit or that of its members." Interpreting this provision, the Commission stated that the test is whether a respondent is engaged substantially in activities which confer a pecuniary benefit upon its members. Applying this standard, the Commission agreed with Administrative Law Judge Barnes that CSMS, NHCMA and AMA were all subject to FTC jurisdiction because they were engaged substantially in activities which confer a pecuniary benefit upon their members.

With respect to CSMS and NHCMA, the FTC noted that "both CSMS and NHCMA have promoted the economic interests of their members through lobbying and legislative efforts, through sponsorship of insurance plans such as the Professional Liability Insurance Program, and through relationships with third-party payers. Moreover, both of these respondents have played key roles in the formation of 'Foundations for Medical Care,' an alternative to HMO's operating on a prepaid basis with fee-for-service physicians." Further the Commission discussed CSMS' development of a relative value guide and use of the guide by the NHCMA peer review committee. Finally, the FTC found that an important pecuniary benefit available to CSMS and NHCMA members was the opportunity to join the AMA, thereby gaining access to pecuniary benefits of AMA membership.

Interstate Commerce. The FTC found that CSMS and NHCMA acted as part of a nationwide conspiracy and therefore their activities affected interstate commerce. In addition, the Commission discussed the substantial volume of public and private funds (government and insurance payments) that came from out-of-state into Connecticut as payment for medical services rendered by CSMS and NHCMA members.

Conspiracy. The FTC found that CSMS and NHCMA conspired with each other, with AMA, and with other medical societies to impose ethical restrictions, and that each respondent conspired with its own members to impose the restrictions (*i.e.*, CSMS conspired with CSMS members, NHCMA conspired with NHCMA members, and AMA conspired with AMA members). The Commission cited the "hierarchical system" whereby members of the AMA's House of Delegates are selected by the

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Summary prepared by Linda L. Randell, Esq., in the law firm of Wiggin and Dana, New Haven, CT. Legal counsel for the Connecticut State Medical Society.

Editor's Note: The Connecticut State Medical Society has acted to continue the appeal through the higher courts.

state societies, and members of the state societies' governing bodies are selected by the county societies. Further, the Commission said, the constitution and bylaws of CSMS, NHCMA, AMA, and most other societies require adherence to the AMA's Principles of Medical Ethics as a condition of membership. It also found that state societies are not permitted to apply principles of ethical conduct which are inconsistent with the AMA's constitution and bylaws. In addition, the FTC stated that the AMA has linked ethical conduct to "local custom" and has urged the county societies to ensure compliance with the Principles of Medical Ethics.

Despite our arguments that CSMS and NHCMA have not adopted the AMA Judicial Council's *Opinion and Reports* (which are interpretation of the Principles of Medical Ethics), the Commission noted that "AMA has stated that county associations are required to apply all of the interpretations contained in the *Opinion and Reports* . . . It is evident, therefore, that the *Principles* and the *Opinions and Reports* play a central role in delineating the ethical standards for physicians in this country." As part of the conspiracy, the AMA provided ethical advice to local societies in specific situations, and complaints were referred by medical societies to one another for action and enforcement of the restrictions.

In essence, the Commission found the existence of a nationwide conspiracy between AMA and other medical societies, and then tied CSMS and NHCMA to that conspiracy. By doing this, the Commission followed a legal doctrine that once the nationwide conspiracy was established, only "slight evidence" was necessary to connect CSMS and NHCMA to that conspiracy. This was a way of avoiding the troublesome issue that there was so little evidence against the Connecticut respondents with respect to enforcement of alleged ethical restrictions. The FTC noted the ties between and among CSMS, NHCMA, and AMA; the adoption of the Principles of Medical Ethics; and noted "the absence of any proof whatsoever demonstrating that CSMS and NHCMA ever took any position in conflict with AMA's challenged restraints." The FTC listed four occasions on which CSMS arguably acted with respect to ethical matters and five occasions on which NHCMA so acted. (The Commission also adopted Judge Barnes' findings with respect to CSMS and NHCMA's "ethical restrictions" as set forth in Barnes' Initial Decision.) While CSMS had not adopted the *Opinions and Reports,* the FTC noted that those policies were "guides" to CSMS. With respect to NHCMA, its bylaws do refer to the AMA's Judicial Council Opinions. Further, the Commission stated that "NHCMA's reliance upon the advice of AMA and AMA's dependence upon NHCMA for enforcement action is well-documented."

The effect of the Commission's finding the existence of a conspiracy is that CSMS and NHCMA are held responsible for each other's actions, the actions of the AMA and the actions of the 2,000 other state and county medical societies, regardless of whether CSMS or NHCMA was aware of those actions.

Restrictions on Advertising and Solicitation. The FTC's discussion focuses on the AMA's *Opinions and Reports,* and the purposes of these ethical interpretations. The Commission held that these "restrictions" have and had "substantial adverse effects on competition," "unreasonably impede competition," and are "unfair methods of competition" in violation of Section 5 of the Federal Trade Commission Act. The Commission's discussion does not directly discuss CSMS or NHCMA, which are tied in by the finding of conspiracy. (See conspiracy discussion, above. Specific "restrictions" were set forth in Judge Barnes' Initial Decision.)

Restrictions On Contract Practice. This discussion also focuses on the AMA's *Opinions and Reports,* concluding that ethical restrictions concerning physicians' contractual arrangements, the adequacy of physician compensation, bidding on contracts by physicians, contracts to deliver services without providing free choice of physicians, non-fee-for-service compensation, and physicians' arrangements with non-physicians constituted unfair methods of competition in violation of Section 5. Again, the discussion relates to AMA and to other medical societies, including CSMS and NHCMA, because of the finding of conspiracy. Thus even though there was no evidence of actions taken against physicians engaged in "contract practice" in Connecticut, CSMS and NHCMA were nevertheless found to be conspirators against "contract practice" nationwide.

Remedy. The Commission modified the Order prepared by Judge Barnes. First, the Commission deleted CSMS and NHCMA from being specifically named in the cease and desist Order. While this might at first seem to indicate that the Commission found that CSMS and NHCMA did not violate the Federal Trade Commission Act, this is not the case. Under the terms of the Order, the AMA would be required to disaffiliate from any society (including CSMS and NHCMA) that did not agree to abide by the terms of the Order. Hence even though the Order is addressed only against the AMA, it effectively binds CSMS, NHCMA, and all other medical societies as well. This was the reason stated for deleting CSMS and NHCMA—the Order effectively reached them anyway. In connection with the Order, the AMA would be required to send a letter to each present AMA member and each State and County medical association, which states in part that "the FTC held that the AMA, the two Connecticut medical societies, and other state and local medical associations have unlawfully restricted the advertising, solicitation and contractual practices of their members in violation of Section 5 of the Federal Trade Commission Act."

The Commission's Order generally prohibits medical societies from interfering with members' advertising, solicitation, contractual arrangements, compensation, and business partnerships with non-physicians. The Order has not become effective and will not become effective during the time that the Commission's decision is on appeal in the federal courts.

The Order does permit medical societies to adopt "reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representations [in advertising or solicitation], that would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act, or with respect to uninvited, in-person solicitation of actual or potential patients, who, because of their particular circumstances, are vulnerable to undue influence." The Commission's opinion underscored its concern that any guidelines be reasonable: "We cannot emphasize too strongly that AMA's discretion with respect to solicitation and advertising is limited to 'reasonable' ethical guidelines. . . . It is especially important that price advertising remain as unfettered as possible. . . . Across-the-board bans on entire categories of representations or general restrictions applicable to any representation made through a specific medium are highly suspect."

Medical Malpractice

In the Chicago, Illinois area, 771 medical malpractice cases were filed in the first nine months of 1979—a 41 per cent hike over the 547 in the same period last year. St. Paul Fire and Marine Insurance Company, which provides malpractice insurance to doctors in 29 states, projects that claims against its policyholders this year will total 3,000, a 13 per cent increase over the 2,663 in 1977.

Jury awards for malpractice cases are up about 15 per cent a year and in some states, more rapid increases are occurring. In New York, the cost to close medical malpractice cases rose 40 per cent or more.

The result is a rapid increase in malpractice insurance rates. Aetna Life and Casualty just hit Connecticut doctors with a 24.5 per cent average premium increase. Hartford Insurance Group has raised rates 20 per cent in Colorado and expects to increase them in Oklahoma and Louisiana. St. Paul has increased rates in 20 of the states it insures. The doctor and hospital-owned mutual carriers have not been affected yet but are expected to be soon.

Causes cited for the increased number of claims and size of awards include a new sophistication on the part of an increasing number of trial lawyers, publicity about high jury verdicts which "whets the appetites of plaintiffs," and an expanded legal concept of medical liability and inflation.

Dr. Robert Berenson of the White House staff replied that the Blue Cross and Blue Shield organizations "were neutral" on a cost containment bill last year but he felt they were "more opposed" this year because they want to rely on voluntary efforts. Both Berenson and Kahn alleged that Blue Cross and Blue Shield efforts to control costs have been hindered by the fact that their boards "are controlled by doctors." Berenson contrasted the Blue Cross and Blue Shield organizations' position with that of the commercial insurers who have supported the cost containment bill "because they don't have those relations" with doctors and hospitals.

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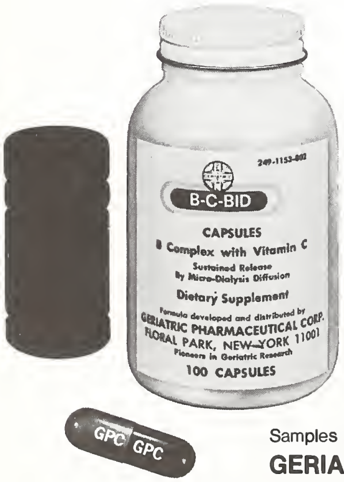
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The Erosion of the Hippocratic Tradition: A Voluntary National Commission Tackles Health Records Confidentiality

ALFRED M. FREEDMAN, M.D.

ABSTRACT—The National Commission on Confidentiality of Health Records has addressed the erosion of the traditional patient-physician trust relationship. Chief problems arise in transferring information to "third party payers," government and employers. Health research also presents data protection problems. Patient access to records is suggested, with third party intervention when there is a physician-patient dispute. Concerted action is recommended to address the problem on a national level.

The National Commission on Confidentiality of Health Records is a federation of some 24 national organizations whose purpose is to preserve and promote the confidentiality of health records. Its members' concern for this significant national problem has been simmering for a long time, but it was during the Watergate years that the American Psychiatric Association, of which I was then President, was shocked into taking concrete action on behalf of patient privacy. Like Senator Sam Ervin, Jr., of North Carolina, the APA was most disturbed when the Daniel Ellsberg—Lewis Fielding episode was investigated by the Senate Watergate Committee, and Nixon Administration officials seemed to feel that breaking into a private psychiatrist's office was a trivial incident.

The American Psychiatric Association convened a landmark conference in the fall of 1974 at Key Biscayne, Florida, where some fifty medical and related organizations came together for the first time to confront health confidentiality issues. In 1976, seventeen national groups, ranging from the American Academies of Pediatrics and of Child Psychiatry to the Blue Cross, American Hospital and Mental Health Associations, coalesced to form the National Commission on Confidentiality of Health Records. Since that time, NCCHR has grown to 24 members, including the National Congress of Parents and Teachers, Planned Parenthood, and the American Statistical Association, and the National Association of Social Workers. It has established itself as a vigorous non-profit organization promoting a fair balance between the patient's right to privacy and society's legitimate needs for personal health information. Through its program of conferences, National Clearinghouse publications, and vigorous participation in legislative and administrative hearings, NCCHR has sought to increase national awareness of health confidentiality problems and obligations.

The Problem

In the two and a half years of the National Commission's existence, we have been distressed by the continuing erosion of the Hippocratic tradition, under which "holy secrets" between practitioner and patient were not to be "noised abroad." This has happened as medical treatment and medical record-keeping have become more complex, as society's demands for personal health data have escalated, as technologies for processing and retrieving information have improved. It is, of course, impossible in today's world to keep health information totally within the private circle of the health-care provider and the patient. Indeed, health care has entered the computer age, and the increased use of personal health data by third parties such as insurers, government agencies, researchers, and employers has

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*Based on testimony presented to the House Subcommittee on Government Information and Individual Rights, April 4, 1979, Washington, D.C.

created a virtual revolution in health record-keeping.

Unrestricted access by third parties, even for legitimate reasons, can cause serious problems for patients if confidentiality is not preserved. This is true of all sensitive health information, but it is particularly true in the field of psychiatry, that medical discipline which deals primarily with the personality of the patient and where trust between patient and physician stands at the core of treatment. Abuse of this trust often makes psychotherapy impossible. Loss of confidentiality is not only embarrassing to the patient—it can lead to serious disruption of family and social life, and even to career and economic damage when confidential information is improperly used to make hiring or promotion decisions, to deny insurance benefits, or to refuse occupational licensing or admission to school.

Third Party Payers

Today, third party payment covers nearly seventy percent of health care costs, including 94.1 percent of hospital expenses and 61.2 percent of physicians' bills. Understandably, private insurance carriers are interested in patient records for underwriting and claims-processing purposes. But insurers often ask for much more information—photocopied hospital records, for example, and highly detailed psychiatric reports—than they really need. In addition, once information is collected it may be widely traded within the entire industry through such groups as the Medical Information Bureau, which holds information on some 11 million people.

Another significant issue is raised when health care is paid for through a group insurance plan, where medical data can often end up in the hands of the patient's employer. As a result, many individuals will not use psychiatric coverage for fear of repercussions at work. Others are mystified when applications for life, health, or disability insurance are inexplicably rejected.

Two examples from NCCHR's correspondence illustrate some of these problems. In one case, a woman who had applied for group insurance was notified that her coverage would be limited because of high blood pressure. Although she immediately protested that she had never had such a condition, the insurance company did not answer her letter or explain how it had obtained the false information. In another case, a young woman was mistakenly diagnosed as an epileptic and was denied insurance based on this mistaken diagnosis. She feared that the information would be indefinitely maintained and that it would render her permanently uninsurable.

Once mistaken, incomplete, or distorted information enters the insurance data system, correcting it can be very difficult. When an application is rejected, the applicant rarely knows why, or how to contest the decision. Patients often write the National Commission that they try to conceal treatment for medical or emotional problems rather than subject themselves to negative assessments of their insurability.

In a very dramatic example of third party abuse a New York physician refused to disclose information about one of his patients to an unidentified woman over the telephone. After several calls, she identified herself as an insurance investigator but still refused to say why she wanted the patient information. Harassment escalated, and the physician said the investigative agency threatened "to open a file on me with the inference that my non-cooperation will now be part of my credit record." Such practices run counter to the recommendations of the Federal Privacy Protection Study Commission which have been adopted by a number of insurance companies, notably Aetna Life and Casualty Co. and Prudential.

Government Access

Government agencies comprise another source of troubling third party demands for personal health information. If health care is financed through state or federal government funds, an extremely complicated system is commonly used to prevent fraud and abuse, control costs and assure a reasonable standard of care.

Health and welfare officials, Professional Standards Review Organizations (PSROs), hospital certification authorities, and fraud investigation units may all receive medical information or seek direct access to patient records, and the vast store of information accumulating in government files disturbs practitioners and patients. In many government agencies, the movement of health information through multiple and often redundant levels of review can receive a higher priority than safeguarding confidentiality, and this seems unlikely to change as the government's role in health care and health insurance expands.

The National Commission's case-letter file holds more letters about government access to health information than about any other issue. Some letters come from government officials themselves, requesting assistance in resolving conflicts between reviewing agencies and practitioners. A state psychological association officer wrote us warning that "civil rights of Medicaid clients are being violated" and that, due to erosion of confidentiality, "many therapists have learned not to keep any progress notes at all as a way of assuring their patients' rights to privacy."

A drug-abuse clinic administrator reported that his clinic's records were reviewed by some ten representatives from five separate government agencies in the course of a year; he felt strongly that this made a "mockery" of confidentiality. He also questioned the qualifications of reviewers who lacked professional training and who "giggled" while examining patient records.

Another dimension of government access is the increase in compulsory reporting to public health authorities. A Florida Community Mental Health Center president strongly opposed a new state regulation requiring compulsory reporting of names, social security numbers, and addresses of all patients. After protests, the state's action was postponed, but the matter has not yet been resolved.

Similarly, a New Jersey hospital administrator raised objections to the increasing government demand for personal and social data, usually for well-intentioned research studies, but all too often through methods which expose the lives of private citizens. He cited particular concern when the New Jersey Department of Health requested detailed information on abortions in a form that could easily lead to the identification of individual patients. "All too often," he said, "the government asks for information it does not really need in the pursuit of better public health."

Employees' Health Records

NCCHR has devoted a great deal of attention this past year to the management of employees' health records. Confidentiality assumes extreme importance in the occupational setting, where loss of a job or a promotion opportunity can bring dire economic and emotional consequences. Health information flows into the workplace through a number of channels, including job application forms, physicals taken by prospective employees, periodic examinations by the employer's medical department, and claims submitted by employees enrolled in group health insurance plans.

Today, occupational health records also provide clues to environmental causes of illness, and are sought by government agencies to detect hazardous substances in the workplace. As a result of comments submitted by the National Commission and other groups the Occupational Safety and Health Administration has developed confidentiality guidelines governing its collection, use, and disclosure of health record information.

However, employers' policies for handling health information vary widely. While some corporations strictly insulate employee health records, others mix medical information with personnel files. Many employers still ask applicants whether they have ever received psychiatric treatment, and many employees fear that medical information obtained by their employer will label them as a future financial risk to the company.

In a recent lawsuit, a Maryland social worker successfully opposed the medical information requirements of the Montgomery County Welfare Department, whose pre-employment form asked such questions as "Have you ever had vaginal discharge?" and "Do you fear heights?" She also refused to give blanket consent to disclosure of her medical records. After litigation in federal court, the intrusive questions and blanket consent clause were removed, and the county made across-the-board changes in its handling of employee health records.

Health Research

Health research presents some of the more difficult balances between patient privacy and society's "need to know"; and research tends to receive special consideration when its information needs conflict with confidentiality. Some researchers have argued that their work deserves a privileged status with relatively unrestricted access to medical records. If such an enclave is created, its members must be carefully defined and an absolute prohibition placed on disclosure of research data for non-research purposes.

One of the most disturbing failures to maintain research confidentiality occurred when the New York State Health Department disclosed the names of some 28 abortion patients in a publicly available report to the National Institutes of Health.

Children and Youth

There are special confidentiality problems where children and youth are concerned. Minors have very real privacy interests that do not always coincide with the interests of their parents. And children have a long, unforeseeable future; facts collected about the health of a two-year-old may remain in his records for seventy years or more. The family physician's or school nurse's record often contains tentative diagnoses, unproven guesses, and developmental data, which in the years to come may acquire a false appearance or objectivity. For example, a child labeled with "minimal brain dysfunction" may have been experiencing slow motor development at age six.

Of course, confidentiality is not always in the interests of a minor—for instance, when parents take steps to prevent evidence of child abuse or neglect from reaching authorities. On the other hand, adolescents have a strong interest in confidentiality when they visit a clinic for birth control counseling, treatment of venereal disease, and other confidential services that the law entitles them to receive without parental consent. Letting parents know about such visits against the patient's wishes may interfere with the minor's right to privacy. Therefore, practitioners should be encouraged to respect a minor patient's need for confidentiality as something separate and distinct from the wishes of his parents.

Patient Participation Rights

One patient commented to NCCHR, "My health records are available for anyone's use or misuse except my own." The current legal situation—with some 13 states providing patients with access to their records in varying degrees—creates unnecessary confusion among the public. How can patients authorize access to their records by third parties if they themselves do not know what the records contain?

When it is necessary to guard against the possibly harmful effects of allowing certain psychiatric or terminally ill patients to see their records, special procedures can be arranged. For example, a third person, preferably a health professional designated by the patient, can decide how much of the record a patient should see. But the need for unusual procedures in special cases should not interfere with providing access as a general rule for those patients who request it.

The Profession's Role

There is a real need for action to address medical privacy issues. There is also a need for practitioners to become more aware of those issues, for their own sake as well as their patients'. The National Commission realizes that it sees only the tip of the iceberg in abuses of health records confidentiality: most patients are not aware of the problem until they experience some direct harm or embarrassment, and even then most are unwilling to complain lest they suffer even further exposure of their personal lives.

Current law at the state and federal level is a patchwork of uneven and ill-defined protection. But new initiatives are afoot: in Illinois last year, with support from a coalition of professionals and concerned citizens, the legislative passed an exemplary mental health confidentiality statute based on the American Psychiatric Association's model law. In other states, similar efforts may succeed if the profession will support them; Connecticut has long had one of the most forward-looking psychiatric confidentiality statutes.

On the national level, both Congress and the Carter Administration are giving serious consideration to the prospect of a comprehensive medical records law, covering hospitals and other federally funded providers. Because of its broad application, such legislation would probably be moderate in tone. But it promises to put a modern legal framework around the greatly expanded use of medical records in today's world. Specifically, the bills proposed by the Carter Administration, by Senators Jacob Javits, (R-N.Y.) and Abraham Ribicoff (D-Conn.), and by Congressman Richardson Preyer (D-N.C.) would call for: (1) more specific notice to patients about disclosures to third parties with or without their consent; (2) patient rights to inspect, copy, and request corrections of their medical records; (3) limits on disclosures to third parties for non-medical purposes; and (4) limits on the government's access to and use of medical records.*

This legislation is undergoing continuous revision; it can and should be improved. As medical practitioners we have a special obligation, to our patients and to ourselves, to assure reasonable, fair, and adequate protection for medical records confidentiality.

*Further information about the legislation before Congress may be obtained from the National Commission on Confidentiality of Health Records, 606 National Press Building, Washington, D.C. 20045 202-347-0900.

Health, Occupation and Education

By occupation, farmers are the healthiest Americans, showing fewer days of restricted activity in 1977 due to illness or injury than ten other types of workers, reports the Health Insurance Institute.

According to Government data, farmers averaged 9.1 days of restricted activity, compared to 11.4 days for white collar workers and 12.4 for blue collar workers.

In an article in *Health Insurance News,* the Institute says that by education the healthiest Americans are those who have had at least sixteen years of schooling—high school and college. Studies indicate persons in this group average 13.5 days of limited activity, compared with 35.6 days by persons with under nine years of education.

Geographically, the healthiest people live in the Northeastern and North-Central regions of the continental United States, averaging 17.3 days of restricted activity, compared to 19.1 in the South and West.

Indications for Aorto-Coronary Bypass Graft Surgery: March 1979

The following is a report prepared by the Council on Scientific Affairs of the AMA and accepted by the AMA House of Delegates at its Annual Meeting in July, 1979.

The Council on Scientific Affairs of the American Medical Association requested a panel of consultants to review the current indications for Aorto-Coronary Bypass Graft (ACBG) Surgery. The consultants considered the place of the operation in coronary artery disease (CAD), but did not consider all the possible applications of the operation in combinations of CAD with other forms of heart disease. They recognized that the decision to operate rests upon the physician's clinical judgment based upon intimate knowledge of all the patient's individual qualities and of the pertinent literature, and careful laboratory studies, as well as the availability of a surgical team of proven capability in ACBG surgery. Nevertheless, it was deemed advisable to review the present indications for the procedure as of January 1979 and some of the relevant background information.

Relief of Angina Pectoris

It is generally agreed that this operation initially provides amelioration of the intermittent pain of angina pectoris in 80 percent to 90 percent of patients who are refractory to adequate medical management; about 60 percent become pain free and an additional 20 percent to 30 percent improve significantly. This successful clinical outcome coupled with a steadily decreasing operative mortality has contributed to the widespread application of this treatment for medically refractory angina pectoris. The ACBG procedure has also been employed in other manifestations of ischemic heart disease (IHD), such as congestive heart failure, arrhythmia, acute myocardial infarction, and prevention of sudden death. It has been suggested that, even in the absence of symptoms, bypassing critical stenotic lesions in terms of both location and patency in subsets of patients might postpone these clinical manifestations and prolong life. Yet despite ten years of experience with this operation, it is apparent that it has not yet been demonstrated in a scientifically acceptable manner to achieve these goals. It has been demonstrated to be an effective operation for the relief of symptomatic coronary artery disease, and in selected situations to prolong life.

One concern with the ACBG procedure has been the discrepancy between symptomatic improvement and the persistence of laboratory evidence for continued myocardial ischemia in a significant number of surgically treated patients. It is possible that various mechanisms (i.e., placebo effect, coronary arterial denervation, or perioperative myocardial infarction) may be partially responsible for the clinical improvement commonly resulting from ACBG surgery. However, metabolic and blood flow studies have been performed by numerous investigators who have documented improved myocardial perfusion and metabolisms in patients with patent grafts, and this appears to be an important factor. Completeness of revascularization and continued long-term patency are important in determining the outcome of this type of therapy. However, certain studies suggest that the initial relief of symptoms subsides with time in an increasing number of patients, apparently due to progression of disease in the native coronary arteries.

Important complications of bypass surgery are perioperative myocardial infarction, graft occlusion, and accelerated atherosclerosis in the grafted arteries. In patient series where evidence of perioperative myocardial damage is actively sought by CPK-MB enzyme release measurement and radionuclide imaging techniques, 25 percent to 30 percent of the patients have evidence for perioperative myocardial infarction. However, if the evidence for infarction is based on rigid electrocardiographic (EKG) and enzyme criteria, the incidence is considerably lower (5 percent to 10 percent). The significance of slight enzyme elevations and/or nonspecific EKG changes in the additional 20 percent to 25 percent of patients is not definitely known. Furthermore, currently used methods of myocardial protection during surgery with cold cardioplegia are resulting in a significantly lower incidence of this complication.

Saphenous vein bypass graft patency primarily depends upon the adequacy of the recipient coronary

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Reports such as this evaluation of coronary bypass surgery do not establish standards of medical practice or care. The standards of medical care change and evolve day by day and locality by locality. In the final analysis, the standards of medical care are established on the basis of all of the facts and surrounding circumstances.

artery distal to the obstruction, but it may also relate to other dynamic circulatory factors and surgical technique. It has been reported following the placement of multiple grafts, that 10 percent to 30 percent of grafts become occluded within the first year and there is continuing additional closure of grafts at a rate of one to two percent per year.

The VA Randomized Control Trial: Left Main Coronary Artery Disease

In a widely discussed effort to evaluate the role of surgical revascularization by ACBG in the treatment of IHD, the Veterans Administration (VA) set up a controlled trial of ACBG in 13 VA hospitals, of 1,464 carefully selected low-risk patients with stable angina pectoris, good left ventricular function, no evidence of congestive heart failure, and arteriographically demonstrable arterial narrowing (> 70 percent) in at least one vessel, 90 patients were found to have significant narrowing of the left main coronary artery. The half of these that were randomized to ACBG surgery had a survival rate significantly higher (92 percent) than that of the medically treated group (76 percent) after six months. This difference has persisted for three years unchanged, and confirmed two earlier less rigorously controlled studies.

The VA Randomized Control Trial: Stable Angina

The 596 patients with stable angina who agreed to cooperate were randomized into groups of 310 medical and 286 surgical patients. The preliminary results after 48 months suggest the survival for that period was not significantly better in operated patients (with demonstrated single or multiple vessel disease and good left ventricular function) than in the medically treated control group. This conclusion confirmed two earlier studies that randomized patients, each in a single institution, between medical and surgical treatment. In the subset of patients with significant triple vessel disease, later data now demonstrate a trend in favor of surgically treated patients. This trend is supported by another controlled study which points to a significant reduction in the occurrence of cardiovascular events over four years in surgically treated patients.

The Surgical Trial Problem

One striking observation that needs to be mentioned in the discussion of surgical trials in general, and of the VA trial in particular, has been the great disparity among surgical teams in mortality rates and in outcome. Unpublished mortality rates for this operation in the New York City area range from 0 percent to 14 percent; in the several contributing VA hospitals it varied from approximately 2 percent to 12 percent. This variance in surgical results is emphasized by the fact that there was one VA surgical group that was able to show, in part because of lower operative mortality rate, a significant benefit in operated patients when compared with randomized controls.

A recent review of preliminary unpublished statistics from several of the more active surgical teams further supports the concept that improved longevity may be accomplished in some surgeons' hands. Some centers are reporting that 80 to 90 percent of their patients' grafts remain open after one year. They are currently claiming about 90 percent five year survival with one to two percent operative mortality—less than one percent in patients without serious compromise of myocardial function. However, these results are not compared with randomized medical controls, and could be influenced by patient selection.

It must further be noted that the VA study patients were operated upon during 1972-74 when fewer multiple grafts were being done and when less operative attention was being given to preparation of the grafts, precise location of the graft insertion site, and minimization of myocardial injury. It is entirely possible that today's best surgical technique provides an answer more supportive of the surgical approach. Indeed, it is fortunate that another multicenter randomized trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI) is currently recruiting patients to examine the outcome over the next five years of medical and ACBG patients from different clinical settings than the VA hospitals; the Coronary Artery Surgical Trial (CAST). It is hoped that the CAST project will benefit from the experience of the VA study.

Unstable Angina Pectoris

Additional studies in selected patients with unstable angina pectoris have failed to demonstrate short term benefit following immediate ACBG surgery. In two carefully randomized studies, one based on a single institution and the other a cooperative multicenter trial sponsored by NHLBI, no significant improvement in longevity was demonstrated in those patients who were operated immediately. However, it must be noted that all patients with left main CAD were excluded from the studies and that a significant percentage of patients later required surgery because of intractable angina. The best approach to the management of unstable angina at present appears to be initial stabilization medically with surgical intervention reserved for those patients who fail to respond to intensive medical management, who remain chronically symptomatic on medical therapy, or who are found to have left main coronary disease.

Unproven Indications for ACBG

There are several other suggested indications for ACBG surgery that as yet remain unproven. These include Prinzmetal's variant of angina pectoris, evolving acute myocardial infarction, cardiogenic shock, ventricular arrhythmias unresponsive to medical management, patients resuscitated after "sudden death," and congestive heart failure due to IHD. Controlled trials are indicated to determine which of these entities might be better treated surgically.

Increasing techniques must be directed to the development of diagnostic techniques that will quantify the relationship between coronary artery obstructive diseases and myocardial function, if there is to be a more rational selection of patients who will benefit by revascularization. The means to broaden surgical competence rest in the medical profession and depend upon research, education, training, specialty certification, and regulation of hospital privileges through peer review. The essence of a profession is its self-regulating capacity in accordance with high ethical and scientific standards.

The primary physician must appreciate that most patients with mild angina pectoris do not require surgical management. It must also be appreciated that the use of ACBG does not lessen the importance of rehabilitative measures and controlling such risk factors as cigarette smoking, hypertension, hypercholesteremia, obesity and sedentary living. Other drug therapy is ususally required as well. The exact indications for ACBG surgery remain under careful and continuing review and cannot yet be precisely stated for most subgroups of patients with IHD at the present time. Further studies of appropriate clinical and artheriographic indications with careful control of surgical technique and patient selection are clearly needed before these issues can be settled; they are currently underway.

Summary and Conclusions

At the present time there is agreement among the Council's consultants that, assuming an acceptable operative mortality rate, ACBG is indicated in symptomatic patients with CAD and ischemia who present:

- — Disabling angina pectoris unresponsive to adequate medical management, with or without myocardial infarction;
- — Critical stenosis of the left main coronary artery; or
- — Triple vessel disease with moderate impairment of ventricular function.

There are several suggested indications for ACBG which are under study but remain to be established. Further research, preferably by randomized control trial, is to be encouraged until more definitive evidence can be developed. These indications include:

- — Other anatomical subsets of IHD than those described above, whether or not symptoms are present
- — Acute myocardial infarction of less than a few hours duration;
- — "Sudden death" with successful resuscitation;
- — Anginal variant due to coronary spasm (Prinzmetal's Variant);
- — Recurrent ventricular arrhythmias;
- — Cardiogenic shock;
- — Congestive heart failure on the basis of potentially reversible ventricular dysfunction;
- — Unstable angina in the acute phase, refractory to intensive medical therapy; or
- — Ventricular aneurysms associated with disabling angina pectoris and/or refractory ventricular tachycardia.

The operation ACBG is relatively contraindicated in IHD patients with:

- — Severe non-reversible ventricular dysfunction;
- — Inadequate coronary arterial runoff distal to critical stenosis;
- — Acute myocardial infarction, without other surgical indication and of more than a few hours duration; or
- — The presence of other serious and untreatable manifestations of arteriosclerotic disease or other advanced debilitating or terminal diseases that are judged by the responsible physician and surgeon to make the risk of surgery unacceptable.

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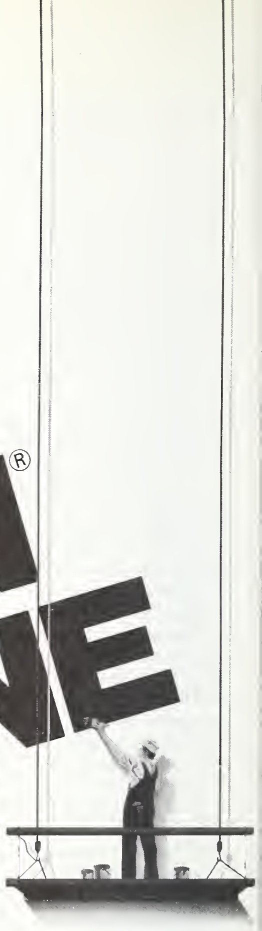

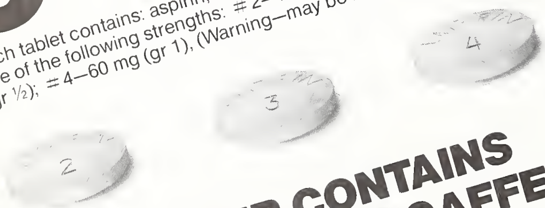

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Reflections from the Dean's Office

Nursing Homes Are Our Business

ROBERT U. MASSEY, M.D.

Medicine is many careers. It may take years for medical students, and later doctors, to discover that there are several lives that physicians may lead by choice or by chance, singly, concurrently, or sequentially. Although there are some careers in which the physician is no longer a physician, most of us follow lives that are extensions of doctoring.

Otto Gutentag, a philosopher of medicine, has called what physicians do the "care of human beings by human beings." That phrase, when it sinks in, may startle medical students into having a new notion, into seeing that the idea of a physician is encompassed entirely by the idea of a human being, and that patients are fellow human beings, not mere objects to be maintained or fixed.

That is not new to those of us on the inside, and the definition is broad enough to cover the many careers of medicine—practice, research, teaching, administration, politics, public health, and public education—as well as all the less formally defined things which physicians may do or be. Physicians as parents may have a special concern for their children's health; as citizens it is natural for them to worry more about the purity of the water supply than about civil rights or court reform.

In the past, physicians, teachers, and clergymen worried about the physical, intellectual, and spiritual health of their communities, and provided leadership to get done those things which they believed were important. Physicians were the first public health officers, and their efforts to discourage quackery and to insure safe food and water were not entirely motivated by self-interest.

Now that the water is safe to drink and the epidemics are gone—at least in the western world—physicians pay less attention to caring for human beings than to the singular form of that definition: a human being caring for another human being. That is as it should be; we can do much more now for the individual patient than we could in 1868 when Virchow was worrying about the sewers of Berlin.

But what about nursing homes in 1979? Here is a problem that some have called our Buchenwald, and yet we seem almost without a glance to turn from it. We, or someone, are warehousing the elderly and the mentally defective in conditions that may be little better than those in Bedlam in 16th Century London. At least the newspapers have hinted something like that almost daily since last summer.

The regulators have said that with their small staffs and limited powers they cannot deal with these problems, especially when there are legal impediments to any kind of action. Anyway, regulatory action is not what is wanted; we need to invent a whole new way of caring for the elderly and the chronically ill.

This may be no more a problem for medicine than the Berlin sewers were a problem for Rudolf Virchow. But surely medicine has more of a stake and a responsibility than the lawyers, legislators, school teachers, and clergy. It is no good to say that the care of the aged is society's problem, let society solve it. Physicians, human beings caring for human beings, clearly have this responsibility to provide the consistent leadership for change. Change toward a higher level can never come from regulations; that is not work for the bureaucracy. Along with the imagination and practical work, this piece of unfinished agenda requires a moral awakening.

There are homes which provide excellent long-term care in Connecticut. Physicians have been active in those institutions, planning them, serving on their boards, and caring for their patients. Nursing homes are an extension of hospitals, a part of the system of inpatient care which is our business. Two ends of one of the diameters of medicine are emergency services and chronic care. We are not the only members on the board, but I believe the others expect us to speak up and offer leadership; everyone else is bewildered.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Rights of the Handicapped: Swords or Shields?

JOSEPH M. HEALEY, J.D.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against otherwise qualified handicapped individuals in federally funded programs solely by reason of their handicaps. Frances Davis, a woman with a hearing disability, sought admission to a nursing program at Southeastern Community College in North Carolina. In the course of her pre-admission interviews it became apparent that she had difficulty understanding questions asked. She submitted to an examination by an audiologist who concluded: (1) that Ms. Davis had a bilateral sensorineural hearing loss; (2) that changes in her hearing aid would enable her to detect sounds almost as well as a person who has normal hearing; (3) but that this improvement would not enable her to discriminate among sounds sufficiently to understand normal spoken speech. She would continue to rely upon lipreading skills for effective communication. The College then consulted the Executive Director of the North Carolina Board of Nursing who reviewed the audiologist's report and concluded that Davis' hearing disability made it unsafe for her to practice as a nurse. Ms. Davis' application was rejected. She asked for reconsideration and the entire nursing staff at Southeastern was assembled. The consultant from the Board of Nursing reiterated her conclusion that the hearing limitations of the applicant could interfere with her safely caring for patients. The application was rejected a second time. Ms. Davis then challenged her denial of admission in the United States District Court for the Eastern District of North Carolina as a violation of Section 504 of the Rehabilitation Act of 1973.

The critical issue facing the Court was interpretation of the statutory language "otherwise qualified handicapped individual." The District Court concluded that this phrase meant otherwise able to function sufficiently in the position sought in spite of the handicap, if proper training and facilities were suitable and available. Since Ms. Davis's disability would prevent her from functioning sufficiently, the Court concluded that the denial of her admission was not discriminatory. Ms. Davis appealed to the Fourth Circuit Court of Appeals who reversed the District Court decision, holding that the District Court had erred in taking Ms. Davis's handicap into account in determining whether she was otherwise qualified for the program. The college should have confined its inquiry to her academic and technical qualifications. The case was appealed to the United States Supreme Court and decided late in the 1978-1979 term.

Mr. Justice Powell delivered the opinion of a unanimous Court.[1] He began by reviewing the history of the statute and of the regulations promulgated under it. Powell concluded that Section 504 stands for the proposition that the "mere possession of a handicap is not a permissible ground for assuming an inability to function in a particular context."[2] In the Court's judgment, "an otherwise qualified person is one who is able to meet all of a program's requirements in spite of his handicap."[3] Schools may require applicants to satisfy appropriate technical and physical qualifications without violating Section 504. On this issue the Supreme Court reversed the finding of the Circuit Court of Appeals.

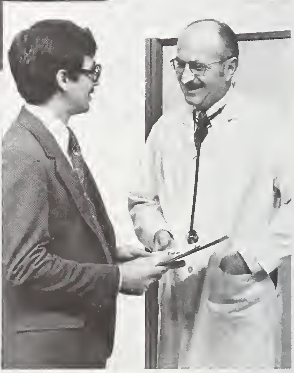
In the case of Ms. Davis, the remaining question was whether the physical qualifications demanded by the College were necessary for participation in the nursing program. Though the Court expressed its awareness that requirements of this sort could become unreasonable or discriminatory, it concluded that such was not the case in this situation. It rejected the claim that Southeastern had a legal obligation to effect substantial modification of its standards to accommodate Ms. Davis. The Court reversed the finding of the lower Court. It held that the standards employed by Southeastern College were reasonable and non-discriminatory.

As interpreted by the Court, Section 504 provides a shield protecting a handicapped applicant from discrimination solely on the basis of the handicap, rather than a sword entitling the handicapped person to claim evaluation without consideration of the handicap. This characterization more adequately recognizes the legitimate interests of both institutions and handicapped applicants and provides a reasonable basis for the establishment and review of admission policies.

REFERENCES

1. *Southeastern Community College v. Davis* (47 LW 4689) (1979)
2. *Ibid.*, 4691
3. *Ibid.*

JOSEPH M. HEALEY, J.D., Assistant Professor of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington, CT.



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EDITORIALS

Drinking, Driving and Implied Consent

In this issue, Attorneys Eisner and Rabkin outline the legal questions surrounding testing for blood alcohol at the request of the police. They conclude that to avoid potential liability, a physician must obtain written informed consent from the individual to be tested.

Certainly all physicians are concerned about such questions of possible liability. Many of us, however, are also concerned about the broader social issue of how to reduce the tremendous toll of limbs and lives for which intoxicated drivers are responsible. We are continually frustrated by the failure of the police to press charges for drunken driving against those who have been involved in an accident and are obviously under the influence of alcohol.

The police alone cannot be blamed for their failure to arrest the intoxicated for drunken driving. The fact of the matter is that the legal and judicial cards are stacked against them. If they arrest someone solely on behavioral grounds, e.g., slurred speech or inability to walk a straight line, the courts will almost never uphold a conviction.

If the police have an elevated blood alcohol level as evidence, their success rate is better. However, blood for alcohol testing cannot be taken against someone's will, as is emphasized by Eisner and Rabkin. Most intoxicated individuals do not voluntarily submit to testing, for obvious reasons. Thus, the police are deprived of the very evidence they need for successful prosecution.

In theory at least, Connecticut's implied consent law is designed to encourage individuals to submit to blood alcohol testing. Anyone who chooses to operate a motor vehicle is considered to have given consent for such testing and will have his operator's license suspended if he refuses.

In practice, however, Connecticut's law is unworkable. It states that for the implied consent penalty to be invoked, the individual must first have been brought to trial for driving under the influence. Only at the conclusion of the trial will the court consider imposing the implied consent penalty.

The "Catch-22" aspect of this law is readily evident. If a driver who has refused testing has nevertheless been successfully prosecuted and convicted of drunken driving, application of the implied consent law is unnecessary since the individual will already lose his license as a penalty for the offense. If, as is more likely in the absence of a blood alcohol level, the prosecution has failed to secure conviction and the driver is declared innocent of the charge, the chances are quite slim that the court will agree to suspend the operator's license for failure to submit to a blood test.

Because of these difficulties, the implied consent law is virtually never used by Connecticut police. Instead, drivers thought to be intoxicated who refuse to have their blood tested are commonly charged with non-alcohol related offenses, such as reckless driving, because of the relative ease in obtaining conviction on these charges as compared with drunken driving.

Attempts to change the implied consent law to make it more workable have been unsuccessful. Senator Howard Owens of the 22nd District introduced legislation at the last legislative session, but it never got out of the Judiciary Committee.

Change in the implied consent law is certainly not the only viable approach to attacking the problem of drinking and driving. It is, however, one avenue which appears potentially productive and yet relatively easy to implement provided it receives sufficient support from enough interested segments of society, such as the medical profession.

We physicians must certainly be concerned about our medicolegal welfare: to not be would be foolhardy. We must, however, not be so obsessed with not getting sued that we lose sight of the broader social and medical problems which confront us.

Gerald L. Springer, M.D.
Chief, Department of Emergency Services
The William W. Backus Hospital
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Letters to the Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.

HMO MOVEMENT IN CONNECTICUT

To the Editor: In *Connecticut Medicine's* article entitled "The HMO Movement in Connecticut" Mehdi Eslami, M.D. and Ellen Seigel, M.A. review the status of HMO activity in Connecticut including a description of the state's HMOs both operational and in planning. The authors have not accurately described the Eastern Connecticut Health Study, Inc. HMO project which they list as including the counties of Windham, New London, and Middlesex seeking a closed-panel model and with an "HMO Status" of "Feasibility application submitted".

Eastern Connecticut Health Study, Inc.'s feasibility project also includes portions of Tolland County (Storrs, Coventry, Columbia) as its study area, and project management has not yet decided on a model (either group practice, individual practice, or a combination of both). The data obtained in the feasibility study will enable the project manager and his board to determine a model. In September both Eastern Connecticut Health Study, Inc. and New London County Foundation for Medical Care were funded by HEW for their respective feasibility studies.

Philip J. Schrefer
Executive Director

Eastern Connecticut Health Study, Inc.
Norwich, CT

The above letter was referred to Dr. Eslami who offers the following reply:

To the Editor: We apologize for inaccuracies in the description of Eastern Connecticut Health Study's service area and organizational model. The source for this information had been the HEW Regional Project Officer, Health Maintenance Organization, in Boston. We congratulate both Eastern Connecticut Health Study, Inc., and New London County Foundation for Medical Care on the awarding of their respective feasibility studies. Announcement of these awards occurred after our article had gone to press.

Mehdi Eslami, M.D.
Ellen Seigel

New Haven County Foundation
for Medical Care, Inc.
Woodbridge, CT

THE NEW HAVEN FOUNDATION

To the Editor: I would like to bring to your attention the difficulty that many of the participating physicians in the New Haven Foundation for Medical Care are having with this organization's curtailing of medical services. The Foundation has embarked on a course of limiting free access to specialists which is directly opposed to the original ideals of promoting free choice for patient and physician.

There are two aspects to this situation. The first is that this physician-sponsored IPA is attempting to ration medical care in a way that is more restrictive than most third party payers. Secondly, if a physician-sponsored IPA is more restrictive than other third party payers there is no question that the other third party payers will soon follow this example. We will become ensnarled in a web of our own making.

I am unsure as to the reportorial resources of *Connecticut Medicine*, but I bring this problem to your attention so that you might consider reviewing the problem for the physicians of Connecticut.

Ronald C. Savin, M.D.

New Haven, CT

The above letter was referred to Dr. Arnold who offers the following reply:

To the Editor: I would like the opportunity to respond to Dr. Savin's letter, which states that the Foundation for Medical Care is preventing free access to its participating physicians, and to clarify the policy of the Foundation Board on the issue of primary and specialty physicians.

In the fall of 1977, the Foundation Board established a policy which stated that all patients joining the Foundation plan be assigned primary care physicians from the list of Internal Medicine or Family Practice, Pediatrics for children, and Obstetrician-Gynecologists for female problems. The Board agreed that this practice was important to prevent patients from acting as their own referents to specialists and to assure proper medical care and cost containment. As to ophthalmology, the Board felt that when there was an injury or disease of the eye, the patient should be allowed to schedule a visit with their ophthalmologist. This policy was reviewed in September of this year, and the Board, in reviewing other Foundations for Medical Care throughout the country, found that those organizations which had not adopted a proper referral system either experienced serious financial problems or were no longer in existence.

The Foundation for Medical Care provides for comprehensive physician coverage which includes office visits, well-baby visits, physical examinations, hospital visits, visits by the physician to the patient's home and all laboratory and x-ray services. Without proper guidelines, it is very possible that a patient who chose to visit five different specialists in one week could do so. The program is attempting to deal with patients who abuse their privilege to medical care and to establish a pattern for medical utilization that makes sense, both from the physician's point of view and the patient's point of view, in terms of assuring the highest quality of medical care and cost containment.

The Foundation, unlike other third parties, does not pay to a fee schedule. Reimbursement is based upon usual and customary fees with a percentile limitation for each specialty being set at the 75th percentile. In comparison with other carriers, with regard to medical coverage and reimbursement, the Foundation can be considered more realistic.

Through various newsletters, the Foundation for Medical Care's participating physicians have been informed of this Board policy. I am happy to state that the Board has received support from both participating primary care and specialty physicians. With respect to this support, the majority of our physicians feel that, in many cases, it is the patient who is abusing medical utilization and, because it is the legal and moral obligation of the physician to see a patient, the patient who has done the self-referring has wasted money as well as the physician's valuable time. Many have gone on to say that this practice by patients can also be dangerous, in that uncoordinated medical treatment can result in the prescribing of many different medications that can be toxic when taken simultaneously. The FMC referral system can prevent such practice. It would, therefore, appear that the participating physicians who are complaining about this policy are small in number. They are predominantly from two specialties, and some of those within these specialties appear to disagree with their colleagues.

The Foundation Board has maintained a policy of being open to participating physicians and subscribers so their points of view can be heard. Dr. Savin is no different in this regard, and he will be addressing our Board at the end of November.

In summation, the Foundation has attempted to listen and to reflect upon the problems of the participating physicians within New Haven County. It has an obligation to the physician members who helped develop the comprehensive benefit program, as well as to the subscribers, who are assured quality medical care when it is needed. It is hoped that these goals will be achieved with the aid of the aforementioned guidelines.

Philip B. Arnold, M.D.
President
and
Peter Aaronson
Executive Director

New Haven County Foundation for
Medical Care, Inc.

Infant Apnea Center

Sponsored by the Connecticut Junior Women, Inc., the Infant Apnea Center has been established to provide continuous medical, technical, and psychosocial support for Connecticut families with infants who have experienced or who are at risk of experiencing apnea. The Center has been reviewed by the National SIDS Foundation, endorsed by the State of Connecticut Program for Sudden Infant Death, and approved by the Executive Committee of the Connecticut (Hezekiah Beardsley) Chapter of the American Academy of Pediatrics.

The Center provides diagnostic services for an infant referred by a physician who considers the infant at risk for apnea; monitoring and medical care for infants identified at risk for recurrent apnea; and supportive counselling to these families.

For further information, contact Dr. Bernard Schachtel, Director, Infant Apnea Center, Bridgeport Hospital, 267 Grant Street, Bridgeport, Connecticut 06602 (384-3711).

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office, Tel.:(203) 865-0587. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street, New Haven, Connecticut 06511

In Memoriam

AMATRUDA, FRANK G., Yale Medical School, 1923. Dr. Amatruda was a general practitioner in the New Haven area since 1924, and during World War II served in the U.S. Army Medical Corps. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; he was also a past president of the New Haven Medical Society. Dr. Amatruda died October 21, 1979, at the age of 81.

WRIGHT, WILLIAM W., Harvard Medical School, 1919. Dr. Wright was a general practitioner in the Hartford area since 1920. He joined the Travelers Insurance Company as a physician in the employees' medical department and served in that department for 35 years, part of that time as director, retiring in 1954. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wright died October 13, 1979, at the age of 89.

BERNANKE, MAX, St. Louis University, 1927. Dr. Bernanke was a internist in the New Haven area since 1947. He was on the visiting staff of the New York Cancer Institute and was an associate visiting physician at Fordham University. While practicing in New Milford, he was associated with the Yale-New Haven Hospital, and was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Bernanke died November 28, 1979, at the age of 76.

VIONI, R. EDWARD, Naples Medical School, 1935. Dr. Vioni was a allergy specialist in the Fairfield area since 1937. He was president of St. Vincent's Hospital and Medical Association in 1945. He received a degree in medicine from Yale in 1946 and the following year he received a degree in specialty in allergy at the University of Illinois. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Vioni died December 3, 1979, at the age of 70.

Month in Washington

The Carter Administration's two-and-a-half year campaign to thwart hospital spending growth has been shot down in flames. by the House of Representatives.

The vote against the Administration and for a substitute bill minus hospital cost controls was a startling 234 to 166, one of the most shattering congressional defeats pinned on President Carter.

The outcome was a resounding victory for the health provider groups that have waged a vigorous campaign against the threat of federal controls limiting hospital expenditures. Leading the fight were the American Medical Association, the American Hospital Association and the Federation of American Hospitals, the principal groups that form the Voluntary Effort (VE) to restrain hospital spending.

Congress was assured by the VE leaders in the wake of the vote that the VE program would continue unabated. "We renew our pledge to the American people and President Carter to fight inflation with every resource at our command," said James H. Sammons, M.D., AMA Executive Vice President.

Dr. Sammons applauded Congress "for its support of the demonstrated ability of the private sector to control hospital costs voluntarily. We assure Congress that its confidence in the private sector has not been misplaced," Dr. Sammons said.

"We are very grateful for this rejection of rationing and regulation," said Michael Bromberg, Executive Director of the FAH. "But the issue will not go away. We must make the VE continue to work."

Alex McMahon, President of the American Hospital Association, said the House action represented an endorsement of the Voluntary Effort. The Administration bill would have "adversely influenced patient care and created a costly addition to the federal bureaucracy," said McMahon.

President Carter said through Press Secretary Jody Powell that the ballgame isn't over. There was White House talk of attempting to revive the measure in the Senate. However, the 68-vote margin of defeat in the House was far too large to raise any serious Administration hope of moving a control bill through the present session of Congress.

The bill approved by the House tagged as the Gephardt Amendment after Rep. Richard Gephardt (D-MO). It establishes a Commission on Hospital Costs to report to the President on success of the Voluntary Effort, on further measures that might be needed to restrain costs, and on long-range strategies on the supply and demand for health care services. It also provides for federal support of voluntary state hospital cost control programs, and the encouragement of philanthropic support for hospitals.

The discarded bill would have imposed federal expenditure controls if the VE failed to keep hospital expenditures increases below 11.6 percent a year. More than 50 percent of the nation's hospitals, including all rural hospitals, would have been exempt. Wage increases for non-supervisory workers would have been taken from the cost equation. So many exceptions were made in efforts to win votes that the measure was viewed by many lawmakers as a farce.

The humiliating defeat for President Carter highlighted one of his glaring problems in office—getting Congress to approve his legislative program. He had made the hospital bill the bellwether of his anti-inflation program and had insisted that its passage was an absolute necessity before serious consideration could be given to national health insurance.

Carter and ex-Health, Education and Welfare Secretary Joseph Califano had berated hospitals for more than two years, accusing them of being "fat and inefficient" and of conducting an intense lobbying campaign against the public interest.

Labor sided with the Administration and conducted a last-minute blitz on Capitol Hill to line up votes, to no avail.

The House vote was preceded by several hours of keen debate. After the Gephardt Amendment won the day, the House was faced with the question of approving the Amendment or nothing. The final vote on passage was 321 to 75.

House Democratic leaders seemed baffled by the Administration's strategy on the measure. They had warned the President and his aides that their nose counts showed that the Administration's bill for standby federal controls didn't have the requisite support in the House. Despite their warnings, the President sent word to schedule a vote, apparently choosing to believe more optimistic predictions from his legislative aides.

The House Rules Committee had delayed the vote for a week after opponents of the bill on the Committee showed surprising strength by refusing to accept the desires of Administration forces for a parliamentary procedure that might have picked up some additional votes.

Unable to secure a rule that would have tied a vote on

Prepared by the Washington, D.C.
Office of the American Medical Association

the Gephardt Amendment to a vote to recommit, thus making the bill's opponents vulnerable to political charges they were against doing anything about the hospital cost situation, Rules Committee Chairman Richard Bolling (D-MO) reluctantly acceded to President Carter's wishes and sent the bill to the floor. The "Rule" granted a separate vote on the Gephardt Amendment.

House Speaker Thomas O'Neill (D-MA), an Administration supporter, told reporters before the vote that the Administration would lose by an "overwhelming" margin, breaking all of the rules of pre-vote strategy. (He later made a stem-winding speech on the House floor in favor of the hospital bill). Similarly, Rules Chairman Bolling was seething when he made clear at the Rules Committee hearing that he was clearing the bill at that time only at the behest of the Administration.

The chief thrust of the opponents during debate was that the Administration measure threatened to impose a new level of burdensome red tape on hospitals that could lead to higher regulatory costs, (a proponent of the bill calculated the cost of the program at $25 million), and that it also would stifle purchase of quality equipment and services and lead to rationing of health care.

A major point was that the VE program had been a resounding success in muting inflation in hospital costs.

Scores of lawmakers rose to attack the Administration plan. Many were Congressmen who battled the plan in the House Ways and Means and House Commerce Health subcommittees. Rep. Gephardt, author of the substitute bill that carried the day, told the House that the main point of his bill "is to keep us on the voluntary path rather than going down the mandatory path." Hospital costs for the first seven months of this year have risen less than the general rate of inflation, he noted.

Rep. Dave Stockman (R-MI), a prominent critic of the Administration plan, said the inflation gap between hospitals and the rest of the economy has vanished since the measure was first sent to Congress, and with the closing of the gap "there no longer is a case for this kind of hastily devised, jerry-built control measure."

Another outspoken foe of the Administration bill, Rep. Phil Gramm (D-TX), noted that 30 state officials are regulating 30 hospitals in Connecticut. If that ratio is applied to the nation, there will be 25,000 federal buireaucrats controlling hospital expenditures, he said.

Rep. David Satterfield (D-VA) highlighted one of the principal concerns of the medical and health professions—that the Administration plan was "a decisive step toward a federalized centrally-controlled and managed health care delivery system."

The House was urged to accept the Gephardt measure and "follow the mandates of the American people who are demanding less bureaucracy" by Rep. James Jones (D-OKLA). "Let us allow the ingenuity of the industry to work to hold down these hospital costs," he said.

Rep. Jim Santini (D-NEV) said the first Administration bill for mandatory caps was "a turkey" and the present bill was "son of turkey."

"I believe that this bill (Administration) has more to do with politics than with regulation," said Rep. Bill Alexander (D-ARK). "I believe that it would add to inflation through another layer of bureaucracy."

Under the Administration plan, said Rep. Thomas Luken (D-OHIO), the HEW Secretary "will have the hospitals of this nation in a vise-like grip."

Rep. Willis Gradison (R-OHIO) said the Administration plan penalized efficient hospitals and promoted "survival of the fattest." If the plan had been in effect in the past much of the life-saving technology and services of hospitals would have been stifled, he said.

Rep. Henry Waxman (D-CA), Chairman of the Commerce Health subcommittee, was a leader in the battle for the Administration bill. He told the House that the moderation in hospital costs was a result of the threat of price controls. There is no assurance the Voluntary Effort will be able to continue its success, he said. The Carter plan "is our chance to say to the American people we are willing to act to hold down the skyrocketing health care costs facing you," he said.

* * * *

The AMA has filed an appeal of the Federal Trade Commission's ruling of October 12, 1979, that the AMA *Principles of Medical Ethics* unlawfully restricts physician advertising.

The AMA's petition to the U.S. Court of Appeals for the Second Circuit, in New York City, contends that the order unlawfully interferes with the rights of medical societies, prohibiting them from disciplining members for overcharging patients, for example. The order would, furthermore, unduly restrict the ability of the AMA and other medical societies to try to curb false and deceptive promotional practices by physicans.

The AMA's appeal contends that the final order went beyond the jurisdiction of the FTC and ignored the Association's efforts to "comply with evolving legal and social standards," concerning advertising by physicians.

The FTC in its order did concede that the AMA has a "unique and valuable" role to play in curbing false and misleading advertising.

The October 12 decision, which was made public October 24, revised an administrative law judge's November, 1978 ruling that would have barred the AMA from any regulation of advertising for two years and that would have required FTC approval for subsequent guidelines.

* * * *

Blue Cross-Blue Shield challenged a Federal Trade

Commission staff study contending that physician influence over Blue Shield plans is "associated with significantly higher fees."

Blues President Walter McNerney said the FTC Bureau of Economics' methodology and results "are not supportable" and are "directly contrary" to the results of a Blue Shield analysis. "Even if the staff's attempt to extrapolate its findings rested on otherwise acceptable methodology, its failure to take account of essential characteristics of the reimbursement system which it analyzed caused the staff to over-state the possible effects of physician influence on Blue Shield plans and total health care costs," said McNerney.

The FTC Report said "our results . . . indicate that reimbursement rates are 16 percent higher where a local medical society or other organized group of physicians selects board members. Furthermore, if physicians, regardless of the method of their selection, comprise 50 percent or more of a Blue Shield board, reimbursement rates are, on average, 10 percent higher."

The Report, prepared by FTC economists David Kass and Paul Pautler, contains a disclaimer that it "has not been reviewed by, nor does it necessarily reflect the views of the Commission or any of its members."

Last May, FTC Bureau of Competition staff called for an open rule-making proceeding to prohibit physician organizations from participating in the control of Blue Shield Plans and to limit for five years individual physician participation to no more than 25 percent of a plan's governing body.

* * * *

State-by-state variations in Medicaid coverage have prompted the Administration to assign high priority to upgrading Medicaid and to move toward making benefits and eligibility uniform across the nation. Despite the estimated $20 billion plus cost of Medicaid during the past fiscal year, serious gaps remain in financing health care services for the poor. One result has been that hospitals and physicians are providing more than $1 billion a year in charity care.

The Administration, whose Medicaid reforms are embodied in its National Health Plan (NHI), has insisted that the Medicaid problem be recognized by the Senate Finance Committee during its mark-up of a Catastrophic National Health Insurance bill. Responding to the plea, the Committee tentatively has approved provisions insuring that the proposed $3,500 "deductible" for out-of-pocket health care expenses be lowered depending upon income.

From 25 percent to 35 percent of the population with incomes below the poverty line—some nine million people—don't qualify for Medicaid. In some states more than 70 percent of the poor are not covered. The differing welfare programs in the states and the need for Medicaid to mesh with these had posed a giant headache. Federal matching Medicaid funds are only furnished for coverage of people who fit specific welfare categories.

There are large loopholes. For example, single adults and childless couples who are poor cannot receive Medicaid unless they are disabled or are more than 65 years old.

Income cutoffs for Medicaid eligibility vary greatly, from less than $2,400 for a family of four in some southern states to $4,800 or above in some northern tier states.

A significant problem is the discouragement to providers stemming from the Medicaid payment rates which average 20 to 25 percent lower than Medicare's rate, a bargain-basement rate, itself.

* * * *

The House had defeated legislation to extend coverage of the National Labor Relations Act to include interns and residents.

The medical profession was split over the question of whether residents should have the right to form labor unions under federal law.

Opposing the concept was the Association of American Medical Colleges because of the possible impact on hospitals affiliated with medical schools.

A principal supporter of the proposal was the AMA, whose House of Delegates took the position that the fact interns and residents "are in a learning process of acquiring new skills does not detract from their legal right to organize and engage in collective bargaining . . . ."

* * * *

Rep. Al Ullman (D-ORE), Chairman of the Ways and Means Committee, has introduced in legislative form a new tax treatment proposal for private health insurance. Ullman is the first lawmaker to propose tightening tax breaks for private health insurance in order to encourage purchase of cheaper insurance, to spur Health Maintenance Organizations (HMOs), and to make health providers and consumers in general more cost-conscious. In a House speech, Ullman said his bill would bring in $3 billion more in federal tax revenues in 1984. The Ullman Plan is expected to be the subject of Ways and Means hearings next year.

Ullman said his proposal would restructure the financing of the health care industry. "It encourages competition within the health industry to offer more economic policies," he said. "It would check and stabilize the rising proportion of the GNP spent on health. By modest estimates, the proposal will reduce health care spending by more than $3 billion in 1984."

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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SUMMARY OF PROCEEDINGS HOUSE OF DELEGATES—SEMI-ANNUAL MEETING

Fairfield—November 15, 1979

Reports and Resolutions

The House of Delegates received reports from the President, the Council, and the AMA Delegates.

Principal Actions Taken

(a) **Report of the President, Edward A. Kamens, Fairfield:** The House VOTED to accept the report of the President which highlighted the need for discussion, by the House, to consider providing funds solely for the purpose of public education efforts to meet the considerable challenges and intrusions confronting organized medicine.

(b) **Budget for 1980:** Following a hearing by the Reference Committee on the budget submitted by the Council, the House VOTED to approve the budget with the following amendments: (a) That the membership dues for 1980 be set at $150.00. (b) that $25.00 of this amount be set aside in the budget as a line item for a public information program, this program to be reviewed by the Council and reported to the House of Delegates.

(c) **Resolution on Elderly Health Screening Pilot Program:** The House VOTED to adopt the following resolution, introduced by the LCMA, with the addition of an amendment relating to the distribution of the resolution:

RESOLVED: That the Connecticut State Medical Society looks with disfavor upon the current "Elderly Health Screening Pilot Program." That copies be sent: Douglas Lloyd, M.D., Commissioner, State Department of Health; Gert M.K. Wallach, M.D., Office of Economic Opportunity, Waterbury; Department of Health, Education and Welfare; and all city governments.

(d) **Resolution on Joint Medicare-Medicaid Program:** The House VOTED to refer the following Medicaid-Medicare program coordination resolution to the Council for further deliberation and action:

RESOLVED: That the CSMS convey to our Congressmen that we favor legislation that would combine Medicare and Medicaid using one current procedural terminology and reimbursement practice.

(e) **Resolution on Honorary Membership for James H. Root, M.D., of Woodbridge:** The House VOTED to approve the Council's recommendation to grant honorary membership to James H. Root, M.D., if and when he departs Connecticut.

(f) **Resolution on the Report of the AMA Ad Hoc Committee on the Principles of Medical Ethics:** Following an in-depth hearing on the subject, the House VOTED to approve the Council recommendations as follows:

RESOLVED: That the report of the AMA Ad Hoc Committee on the Principles of Medical Ethics be referred to the Judicial Committee of the Connecticut State Medical Society for study and report back to the Council in time for presentation to the CSMS House of Delegates at the next annual meeting. It was further VOTED that the membership be urged to make recommendations to their representatives on the Judicial Committee prior to the committee's final deliberations.

(g) **Resolution on the Blue Cross-Blue Shield Medicare Proposal:** The House VOTED to adopt the following resolution after a hearing on the subject:

RESOLVED: That the Connecticut State Medical Society encourages the continuation of open, equal and free competition within the health insurance industry so as to offer our patients a multiplicity of available coverages, so that they themselves may determine which are the most beneficial and cost effective.

RESOLVED: That the Society deplores any attempts to reduce or eliminate such competition by the issuance of large financial "planning" grants to solitary insurance carriers in order to hide the true costs of potentially monopolistic and restrictive programs.

(h) **Resolution on the Connecticut Medical Examining Board:** Following discussion concerning the subject the House VOTED to adopt the following resolution:

RESOLVED: That the House of Delegates urge the Council to continue to pursue cooperative efforts with the Connecticut Medical Examining Board to assure its proper functioning following the Sunset Law revision process.

(i) **Proposed Amendment to the Bylaws:** The following proposed amendment to the Bylaws was presented to the House and placed on the table for consideration and action at the next regular meeting of the House of Delegates.

Proposed Amendment to the Bylaws: Amend Article V, Section II, to read: A quorum at any meeting of the House of Delegates shall consist of a majority of the sum of the number of delegates eligible to vote in the House.

Presentations and Awards

(1) **To CSMS Officers and County Councilors for Past Services:**

OFFICERS:

Charles M. Krinsky, New London—Vice Speaker; Isadore H. Friedberg, Hartford—Councilor-at-Large; E. Tremain Bradley, New Canaan—Alternate Delegate and Delegate to AMA.

COUNCILORS:

Hartford County — Joseph S. Sadowski, Hartford — Councilor; Irving I. Rosenthal, Bloomfield — Associate Councilor; Trudeau M. Horrax, Farmington — Associate Councilor. *Litchfield County* — Robert W. Harkins, Woodbury — Associate Councilor and Councilor. *New London County* — Charles M. Krinsky, New London—Associate Councilor and Councilor. *Windham County*—William M. Shepard, Putnam—Associate Councilor.

(2) **Special Award:**

James H. Root, Jr., Woodbridge, Presented with a framed resolution outlining his dedicated and valuable efforts over the past twenty years on behalf of the Society, including President in 1974, President of Waterbury Medical Association in 1970, and New Haven County Medical Association in 1971, and for his devotion as Medical Director of the Professional Standards Review Organization II, Inc.

Four doctors were recipients of Service Awards during the recent Semi-Annual Meeting of the Connecticut State Medical Society at Ottavio's in Fairfield.

Right to left—Dr. James H. Root, Jr., of Woodbridge, who received a special award for Dedicated and Valuable Service; Dr. Trudeau M. Horrax of Farmington, was honored as Associate Councilor 1977-1979. In the center, the President of the CSMS who presented the awards, Dr. Edward A. Kamens, of Fairfield; Dr. Joseph S. Sadowski, of Hartford, recipient of the Councilor's Award 1977-1979; and Dr. Charles M. Krinsky, New London, who was honored with an engraved silver Revere Bowl as Vice Speaker of the CSMS House of Delegates, Associate Councilor 1972-1973 and Councilor 1973-1979.

Missing from photo is Dr. William M. Shepard of Putnam, Associate Councilor 1978-1979.

Other Service Award recipients who were not present are Dr. Isadore H. Friedberg, of Hartford, Councilor at Large 1978-1979; Dr. E. Tremain Bradley of New Canaan, Alternate Delegate to the AMA 1969-1972 and Delegate to the AMA 1973-1979; and Dr. Irving I. Rosenthal, of Bloomfield, Associate Councilor 1978-1979.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Part-time position available at Wesleyan University Health Center for physician specializing in Internal Medicine, Family Practice or Pediatrics. Contact Helen Davis, M.D., FAAP, University Physician, Wesleyan University, Middletown, CT 06457. (203) 347-9411, ext. 217 for further details.

EMERGENCY ROOM

We are seeking physicians or emergency treatment corporation to own and operate emergency treatment facility in large Medical Office Building. Strong Demand. Contact D. Delaripa, Medical Center, Ltd., 131 New London Tpk., Glastonbury, CT 06033. (203) 659-1371.

Emergency Physician-full time position available in modern 226-bed community hospital in eastern CT; 33,000 visits yearly; 42-hr. work week; salary negotiable. Send CV to G.L. Springer, M.D., Chief of Emergency Services. W. W. Backus Hospital, 326 Washington St., Norwich, CT 06360.

FAMILY PRACTICE

Family Practice residency graduates wanted July '80 to join a 3 doctor group with unique make-up. Two recent residency graduates and previous Director. UConn residency. Hospital-sponsored group practice will grow to 6 doctors plus Nurse Practitioners and Health Educator. Serves area of family doctor shortage, yet only 10 miles from New Haven and one hour from New York City. Competitive salary and fringes. POMR. Family practice involves active in-patient, medical and pediatrics, no OB. Tertiary level consultation at two Connecticut Medical Schools. Contact Dr. John Donnelly (203) 929-7331.

Family Practice or Internal Medicine: Established first floor professional office space. Approx. 1700 sq. ft., and attractive residence. Center of Branford. Available for sale or lease. Call (203) 488-0244.

The only Family Physician in a lovely southeastern Ct. town of 18,000 people wishes to retire from a well-established practice. Access to Thames River, L.I. Sound, industries and resorts. Positions of industrial physician, school physician, and medical examiner are open, as are privileges at two nearby hospitals. No charge for transfer of the practice. Home, office, land, furniture equipment and supplies available for lease or purchase, with owner financing available, as well as possibility of community encouragement. Call (203) 848-3415.

OBSTETRICS-GYNECOLOGY

Male or female, board eligible, associate wanted to join busy solo PC practice in large Ct. city, all facets of our specialty. Send CV to OB/GYN-BP.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

ALLERGY

Allergy-Internal Medicine: July '80. Age 28. FLEX. Cert.-IM; Elig.-Allergy. MD: India. Int. and res.: Jamaica Hosp., NY. Fellowship: St. Univ. of NY-Buffalo. Willing to do part-time IM. Wishes grp., assoc., or institutional practice in large or med. community. Desai G. Krishnarao, M.D., 770 West Ferry, #11B, Buffalo, NY 14222.

ANESTHESIA

July '80. Age 29. Conn. license pending. AB-elig. MD: India. Int.: Kings County Hosp., NY. Res. and fellowship: Albert Einstein. Wishes grp. or assoc. practice in large or med. community in Ct. Mukesh N. Gatha, M.D., 1935 E. Chestar Rd., Apt. #22C, Bronx, NY 10461.

Anesthesia-General Practice: Jan. '80. Age 48. Conn. license. AB-elig. Presently in practice. 16 yrs. experience, trained in Ct., and residing in the state, available for coverage, long locum tenens, or full time. Call 227-1484.

Available now. Anes. or GP. Age 43. Conn. license. AB-cert. MD: Univ. of Southern CA. Int.: Roosevelt Hosp., NY. Res.: St. Luke's Hosp., and Columbia Presbyterian Hosp., NY. Part-time work in GP or possible clinic. Held full-time, non-clinical position in the pharmaceutical industry for 5 yrs., interested in breaking into practice gradually. Contact CSMS/Anes.-GMR.

FAMILY MEDICINE

Aug. or Sept. '80. Age 28. Nat'l. bds., elig. MD: Univ. of PA. Int. and res.: Thomas Jefferson Hosp., PA. No Ob. Prefers location near Guilford, but will consider other areas. Rural or sm. town. Prefers to practice with or near husband (Fred Markham, M.D.) also Family phy. Grp., assoc., institutional or industrial practice desired. Anne L. duBreuil, M.D., 950 Walnut St., Apt. #310, Barringer Hall, Philadelphia, PA 19107.

Jan. '80. Age 30. Nat'l. bds. MD: UConn. Int.: Lacrosse Lutheran Hosp.-Gundersen Clinic, Wisc. National Health Service Corp., ND. Looking for grp. practice in small community. Looking for permanent location but will need leave of absence from 9/80-6/81 for further training. Will consider temporary placement until 9/80. Timothy M. Empkie, M.D., c/o Vittum, 225 Vernon Ave., Glencoe, IL 60022.

Aug. or Sept. '80. Age 28. Nat'l. bds., elig. MD: Dartmouth. Int., res. and fellowship: Thomas Jefferson Hosp. No Ob. Prefers location near Guilford, but will consider other areas. Rural or sm. town. Prefers to practice with or near wife (Anne L. duBreuil, M.D.) also Family phy. Grp. assoc. institutional or industrial practice desired. Fred W. Markham, M.D., 950 Walnut St., Apt. #310, Barringer Hall, Philadelphia, PA 19107.

INTERNAL MEDICINE

Available May-Sept. '80. Chest Diseases. Conn. license. MD: St. Louis Univ. Int.: Yale New Haven Hosp. Res.: US Public Health Service. Fellowship: Marine Hosp., Staten Island and Holley State Hosp., Fla. Presently in practice. Looking for a locum tenens. Herman S. Cutler, M.D., 3460 S. Ocean Blvd., Palm Beach, FL 33480.

Cardiology: July '80. Age 35. FLEX. AB-cert. MD: Berlin. Int. and res.: Mt. Sinai Hosp., CT. Fellowship: SUNY-Buffalo. Wishes solo, grp. or assoc. practice in CT. Martin P. Echt, M.D., 34 Tomcyn Dr., Amherst, NY 14221.

Cardiology: Available anytime. Age 38. Conn. License. AB-elig. MD: Philippines. Int.: Watts Hosp., NC. Res.'s.: Misericordia-Fordham and St. Clare's Hosp., NY. Fellowship: St. Clare's Hosp., NY. Institutional or clinic practice 9-5 in med. community in Ct. Contact CSMS/IM-Card.-RCE.

Gentamicin: Clinical Role

DAVID L. COLEMAN, M.D., AND JOHN L. RYAN, M.D., PH.D.

An understanding of the clinical manifestations and therapy of gram negative bacterial infections is becoming increasingly important. The prevalence of gram negative infections has increased as therapeutic advances have permitted improved survival in patients with chronic diseases such as cancer, renal failure and diabetes. The group of aminoglycoside antibiotics in general, and gentamicin (Garamicin®) in particular, have become the mainstay of therapy for serious gram negative infections. At present, 7-10% of all hospitalized patients receive an antibiotic and 3-5% of all patients receive gentamicin. The clinical indications for the use of gentamicin and appropriate methods of monitoring therapy are of paramount importance to the clinician. This review will discuss several practical considerations in the safe and efficacious use of this antibiotic. The reader is referred to several extensive reviews[1 2 3 4] for additional information.

Gentamicin was first reported in 1963[27 28] as a derivative of the submerged fermentation products of several micro-organisms in the genus Micromonospora purpurea and the family Actinomycetales. Gentamicin is a polar amino sugar which acts directly on the bacterial ribosome to impair translation of the genetic material and cause defective protein synthesis[1 26]. Clinically, this results in the killing of bacteria in all phases of cell growth and confers a bacteriocidal effect.

Pharmacokinetics

The polarity of gentamicin prevents it from being effectively absorbed across lipid membranes. Therefore, absorption from the gastrointestinal tract is negligible. Effective serum levels can only be achieved after parenteral administration. Gentamicin is radidly absorbed from intramuscular injection sites with peak levels achieved 45-60 minutes after injection. The drug has a volume of distribution corresponding to the extracellular space. It is bound weakly to plasma proteins (30%) and to erythrocytes (10%), with the majority present in solution (60%).[5]

Gentamicin achieves levels in urine 30-fold higher than those in the serum.[6] Levels in the bile,[7] peritoneal and pleural fluid[6] are usually ¼ to ½ simultaneous serum levels but are therapeutically sufficient in most situations. Penetration into the inflamed meninges is incomplete and should not be relied upon.

Gentamicin is excreted unchanged by the kidney. About half of an administered dose can be recovered from the urine within 24 hours, and about 90% ultimately. The half-life in the presence of normal renal function is 2 hours. Clearance is impaired in the presence of decreased creatinine clearance and it is increased in patients with burns.[8]

The dose employed for most infections is calculated on the basis of ideal body weight.[4] In obese patients, the dose should be modified by adding 40% of the difference between total weight and ideal weight to account for the distribution of gentamicin in adipose tissue.[31] The loading dose is 1.5-2.0 mg/kg regardless of the patient's renal function. A loading dose is utilized to achieve prompt therapeutic blood levels by saturating tissue and protein binding sites. If a bolus of 2 mg/kg is used, 90% of patients will have a peak serum level greater than 4 μg/ml which is believed to be efficacious for most infections.[9] A maintenance dose of 1-1.5 mg/kg of body weight is administered every eight hours in the presence of a normal creatinine clearance. In renal failure, when the serum creatinine is less than 3 mg/dl the dose is adjusted by giving 1-1.5 mg/kg at an interval obtained by multiplying the serum creatinine by eight hours. If the serum creatinine is greater than 3 mg/dl the dose should be reduced in proportion to the creatinine. The dosing interval should not exceed 24 hours to avoid prolonged periods during which the trough gentamicin level (see below) is in a subtherapeutic range. An alternative approach is to reduce the dose in proportion to the serum creatinine and keep the interval at eight hours. While there is no convincing evidence to support either approach as being less toxic

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or more efficacious, the former regimen is usually employed to achieve adequate peak levels.

The use of the serum creatinine to determine dosing interval has several possible pitfalls:

1. Renal function may be in a dynamic state and may not be adequately reflected by a single static creatinine measurement.
2. Occasionally there may be a poor correlation between serum levels and dosing regimen based on serum creatinine.[11]
3. If the serum level is below the minimal inhibitory concentration of the offending organism for greater than six consecutive hours between doses, the dosing interval should be decreased.
4. As mentioned above, clearance of gentamicin is increased in burn patients and higher doses should be employed.

The aforementioned problems in dosing and the small toxic to therapeutic ratio necessitate the measurement of serum levels in monitoring therapy with gentamicin. Serum gentamicin levels may be measured with a variety of techniques[4] but the two major methods presently used are the radioimmunoassay[25] and the agar gel diffusion bioassay.[24] The radioimmunoassay is rapid, sensitive, and specific but expensive unless large numbers of specimens are being processed. The bioassay is cheap and accurate, but is slow and is affected by a variety of factors (heparin[12], pH,[30] Na+ concentrations[16] and Mg+ concentrations[17]).

Peak serum levels are obtained 30-40 minutes after a parenteral dose and trough levels are measured just prior to the next dose. The peak levels should be maintained between 4 and 10 μg/ml and the trough levels at less than 2 μg/ml. We often measure peak levels on the second day of therapy to insure a safe, efficacious level between 4 and 10 μg/ml. The trough level is usually measured on day #2 and again on day #5 to insure that trough levels are being maintained below 2 μg/ml. The dose is adjusted according to these peak and trough levels. The following table shows sample results and appropriate manipulation of the dose:

	PATIENT		
	A	B	C
Day #2			
Peak	2 μg/ml	6 μg/ml	4 μg/ml
Trough	1	3	1.5
Revision:	Increase dose 2 mg/kg/day	Reduce dose 1 mg/kg/day	Leave on present regimen
Day #5			
Peak	14	6	5
Trough	2	1	3
Revision:	Reduce dose, same dosing interval	Leave on present regimen	Increase dosing interval by 4 hours then recheck trough level

(Samples of peak and trough levels on Day #2 and #5 of therapy in three patients (A, B, C) with normal renal function.)

Clinical Indications

Gentamicin is active against most gram negative bacteria including E. Coli, Proteus sp., Citrobacter sp., Enterobacter sp., Serratia sp., and Pseudomonas aeruginosa. Gentamicin has little or no activity against anaerobes, Neisseria sp., and Hemophilus sp. The activity against gram positive organisms is predominantly limited to Staphylococcus aureus but penicillin and gentamicin have been shown to be synergistic against enterococcus[3] as will be discussed below.

Any patient suspected of being septic, particularly from a genito-urinary, biliary or gastrointestinal source, should have an aminoglycoside such as gentamicin as part of their initial antibiotic regimen, pending culture results.

Surgical and traumatic wound infections, when due to specific organisms may also be effectively treated with gentamicin. However, gentamicin alone is usually not adequate for mixed wound infections because of the likelihood of gram positive organisms other than Staphylococcus aureus and anaerobic bacteria.

Gentamicin is also very useful in the therapy of hospital acquired pneumonias, particularly those in an immunocompromised host in whom a pneumonia caused by gram negative organisms is more likely. Patients with structural pulmonary disease (eg. impaired drainage due to an obstructing carcinoma) or with impaired immunocompetence will not respond as well as patients with uncomplicated infections.[15] In this situation it is particularly important to pursue a specific etiologic agent.

Approximately 90-95% of organisms implicated in urinary tract infections are sensitive to gentamicin. However, most of these organisms will respond to much less toxic agents such as nitrofurantoins, ampicillin and sulfonamides. Because of high levels achieved in the kidney and urinary tract, dosing once or twice per day has been shown to be equally efficacious to a three times per day dose schedule when gentamicin is specifically indicated for a urinary tract infection.[14]

Gentamicin is useful in the treatment of gram negative meningitis or ventriculitis only if 4-5 mg is administered intrathecally or through an Ommaya Reservoir every 24 hours in addition to parenteral therapy.[29] It is also useful in selected cases of gram negative osteomyelitis, keratitis, arthritis and endocarditis.

Toxicity

The toxicity of gentamicin is principally renal and to the eighth nerve. The ototoxicity occurs at a prevalence of 2-3%. The main risk factors for the development of ototoxicity are renal insufficiency and concomitant use of other ototoxic drugs such as furosemide or ethacrynic acid. The eighth nerve toxicity is principally vestibular (67%), occasionally auditory (16%) or both (17%).[18] The development of ototoxicity cannot be accurately predicted on the basis of daily dose, total dose, duration of therapy, or serum levels of gentamicin. Ototoxicity can be measured using caloric testing, audiometry or electronystagmography but is impractical in most clinical settings. Unfortunately, the ototoxicity is often irreversible.

Nephrotoxicity occurs in 2-10% of patients[19] and is rarely seen before one week of therapy. It is usually manifested by dose related nonoliguric renal failure characterized by a gradual decrease in renal function. This is usually reversible over the course of several days to weeks upon discontinuing the drug. The development of nephrotoxicity has been correlated with trough levels greater than 2 μg/ml.[20] Renal failure due to gentamicin may be potentiated by other nephrotoxins such as methoxyfluorane[21] or cephalosporins.[22]

Nephrotoxicity is often heralded by the presence of proteinuria and cylindruria. The urinalysis is useful and inexpensive to follow in-patients on gentamicin and is a helpful adjunct to the measurement of serum gentamicin levels, serum creatinine determinations and creatinine clearance.

Other, less common, adverse reactions described with gentamicin are an enhancement of neuromuscular blockade in patients on curare-like drugs, an acute organic brain syndrome,[23] maculo-papular skin eruption and abnormalities in liver function tests.

Over the past ten years the clinical role of gentamicin has expanded. Several exciting applications of this potent antibiotic have recently been developed and are currently under investigation. The combination of penicillin and an aminoglycoside has been shown to be synergistic against Enterococci. Because of increasing resistance to high levels of streptomycin, the combination of penicillin and gentamicin is now recommended for the therapy of endovascular infections due to enterococcus.[13]

Gentamicin has also been incorporated into polymethylmethacrylate beads and acrylic cement to reduce infectious complications of arthroplasty.[33] In a study from Germany, employment of this adjunct to arthroplasty reduced infectious complications by a factor of 10.[34]

Finally, in recent experiments using a rat model of pyelonephritis low doses of gentamicin have been shown to achieve concentrations in the kidney sufficient to prophylax against the development of renal parenchymal infection.[32] While there is no clinical data to support the usefulness of this protocol, it confirms that new uses may yet be developed for this antibiotic.

Gentamicin is a highly effective antimicrobial agent with a definite role in the therapy of selected bacterial infections. In the future, gentamicin's role in the therapy and prophylaxis of certain infections may increase. The specific clinical indications and need for dose monitoring must be understood by all physicians to safely utilize this agent which should result in the delay of the emergence of resistant strains and in a decrease in drug related toxicity.

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Surgery for Epilepsy: Role of Depth Electroencephalography

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ABSTRACT—Despite recent advances in diagnosis and treatment, control of epilepsy remains unsatisfactory in more than 30% of patients. If an epileptogenic focus can be identified in these uncontrolled patients, excision provides a 60-80% chance of complete or near complete seizure relief. Techniques such as depth electroencephalographic recording improve localization of seizure foci, thereby decreasing the 20-40% surgical failure rate and providing more epileptic patients this therapeutic option. The program in operation at Yale Epilepsy Center is utilizing this and other techniques in delineating surgical candidates with medically refractory epilepsy. Illustrative cases are presented to demonstrate how management can be improved with the information acquired by these methods.

Epilepsy affects at least one million people in the United States.[1, 2] Even the most optimistic estimates indicate failure of seizure control in 30% of epileptic patients[3]. Thus, despite significant advances in the past decade including the ability to monitor serum anticonvulsant levels, the introduction of two new drugs for control of seizures, and the improved ability to diagnose epilepsy using sophisticated techniques for continuous audiovisual and electroencephalographic monitoring, seizures remain uncontrolled in 300,000 persons in the United States.

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Approximately two-thirds of these medically refractory epileptic patients have focal epilepsy, and in them, surgical procedures constitute an option when medical management fails. According to the recent report of The Commission for the Control of Epilepsy and its Consequences[1], "It is estimated that more than 100,000 persons with epilepsy might be helped by neurosurgery. Only 200 to 300 persons per year currently receive this treatment, which relieves seizures in 60-70% and returns 20% to employment." Since 90% of patients with epilepsy are cared for by primary care physicians,[1] the manner of evaluation and selection of medically refractory epileptic patients for surgical intervention is a timely issue of general interest and importance.

Background

Many surgical procedures have been attempted to control epilepsy; trephination in prehistoric skulls may have been such an attempt.[4] None have remained as well established as cortical excision of epileptogenic foci. Though of earlier use, the technique as presently practiced owes its origin to the procedures done after World War I by Otford Foerster.[5] The development of clinical electroencephalography in 1929 by Hans Berger[6] and the demonstration of electrocorticography in 1935 by Foerster and Altenberger[7] were the next major forces in the refinement of epilepsy surgery. Penfield studied Foerster's surgical specimens and continued his pioneering in this field[8] aided by Jasper's clarifications of the electrical activity in epileptic brains.[9] In 1951, the publication by Bailey and Gibbs[10] of cortical excision guided by lateralization of seizure focus on the basis of electroencephalography alone was the culmination of the efforts of these pioneers and the beginning of the modern era of epilepsy surgery.

Numerous reports have confirmed that cortical excision is of benefit in the treatment of focal epilepsy refractory to anticonvulsant medications. Overall, excision of well-designated epileptic foci results in complete or near complete seizure relief in 60-70% of patients.[11-17] In a comprehensive review of the world literature on this subject covering more than 2,000 operations between 1928 and 1973 for intractable epilepsy, Jensen[17] has shown 50% of patients seizure free and 18% with marked reduction in seizures. The consistency of benefit over long periods of time confirms the value of surgery for refractory epilepsy.

A majority of patients with focal intractable epilepsy who are selected for surgery are thus significantly benefitted by surgical therapy. Although series vary in terms of criteria for selection, grouping, and reporting, a 60-80% success has been repeatedly confirmed. The 20-40% failure rate implies that either no surgery should have been done or a different excision was indicated.

Limitations

Most often, surgical failures are attributed to insufficient resection or to insufficient localization.[4,18] For example, in Van Buren's series of patients undergoing surgery for intractable temporal lobe epilepsy,[12] the failure rate was 20% in patients undergoing total temporal lobe resection in contrast to a greater than 50% failure rate in patients with partial temporal lobe resection. Most surgeons perform epilepsy surgery with these facts in mind. Standard "complete" temporal lobe resections are generally done in cases of temporal lobe epilepsy that reach surgery; and cortical excisions elsewhere are limited by the extent of likely neurological deficit.

There remains the possibility of improving surgical success and maximizing utilization of surgery by improving localization of seizure foci. A marked decrease in surgical success is obtained in patients with multiple or bilateral epileptogenic foci.[19,20] Since patients with multiple foci are not good surgical candidates, any means that can detect such patients among the presumably unifocal group should improve epilepsy surgery results. Conversely, any means that can detect unifocal disease among the presumably multifocal group, or foci not localized by scalp EEG recording, would improve our ability to treat medically refractory epilepsy. The issue of how to sufficiently localize epileptogenic foci is not entirely resolved, but ongoing programs and studies have provided much needed information regarding more precise selection of epileptic patients for surgical intervention.

Selection Criteria

Basic initial selection criteria followed by most Epilepsy Centers having an epilepsy surgery program include: 1) failure to control seizure with an adequate trial of anticonvulsant drugs; 2) significant interference by seizures with the patient's life; 3) possibility of surgical removal without production of unacceptable neurological deficit; and 4) evidence of focal origin of attacks.[21,22] The evidence of focal origin is sometimes difficult to establish. Although neurologists and neurosurgeons who select patients for surgery always try to define the exact extent of any focal epileptogenic lesion, the means by which this is done vary. Most institutions utilize refined neuroradiological techniques including angiography, pneumoencephalography, and CT Scanning; extensive neuropsychological evaluation; and electroencephalography with nasopharyngeal and sphenoidal recordings as parts of the standard evaluation. The direct recording of spontaneous seizures from the scalp may be accomplished with the newer techniques for continuous audiovisual and electroencephalographic monitoring, but is often not sufficient to localize or even lateralize seizure onset. Finally, the electrical recording of spontaneous seizure onset and discharge from the depths of the brain is felt by some epileptologists to be the best possible evidence of seizure focus.[23-27]

Depth Electroencephalography

The placement of intracerebral (depth) recording electrodes, practiced most extensively in Paris by Talairach and his group[28,29] is now performed by several centers in this country, including the Yale Epilepsy Center. The depth electrodes used here are constructed by laminating 18 platinum-iridium wires around a length of 24 gauge thin-walled stainless steel needle. One electrode contact per wire is created by cutting through the insulation at designated points.[30] Electrodes are placed stereotactically at sites determined by the patient's clinical and electroencephalographic presentation. Cerebral regions that have been most consistently studied include anterior temporal, medial and orbital frontal, and hippocampal regions bilaterally (see Figure 1). The risks of placing intracerebral electrodes include infection and hemorrhage. In general, our experience as well as that of other Epilepsy Centers indicates that complications occur infrequently and are usually readily treated.

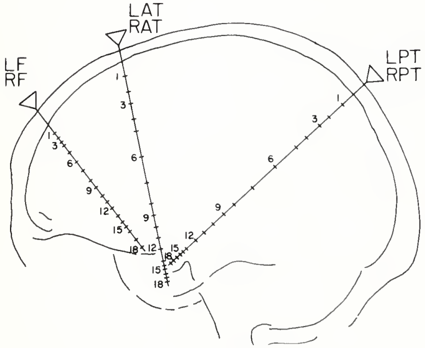

Figure 1

Depth Electrode Placement

LAT = Left anterior temporal electrode
RAT = Right anterior temporal electrode
LF = Left frontal electrode
RF = Right frontal electrode
LPT = Left posterior temporal electrode
RPT = Right posterior temporal electrode

Many case reports document the information to be obtained by the placement of depth electrodes.[24,31-37] Electrical activity observed in the depths of the brain may not be seen in simultaneous scalp recordings; a typical example from the Yale Epilepsy Center demonstrates this (see Figure 2). Depth electroencephalography is a means by which more precise localization can be performed. Unilateral abnormalities projected bilaterally to the scalp can be identified; such patients are potential surgical candidates who are not otherwise identifiable. Unsuspected multiple foci can be detected; these patients would be spared unnecessary surgical procedures.

Careful review of the literature as well as pilot data from this Center suggest that depth electroencephalography is a critical addition to the evaluation of potential surgical candidates, that it alters the treatment of many patients so studied, both by detecting additional surgical candidates and by identifying some inappropriate ones, and that its benefits outweigh its risks.

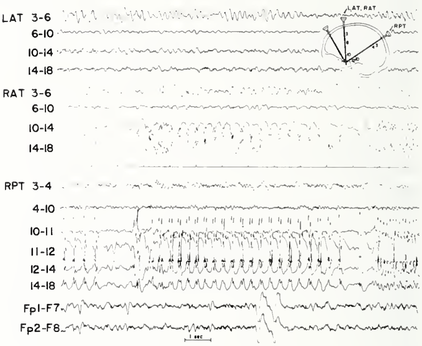

Figure 2

Seizure discharge in depths of brain without concommitant surface seizure activity.

LAT	Left anterior temporal electrode
RAT	Right anterior temporal electrode
RPT	Right posterior temporal electrode

Numbers designate electrode contacts from superficial (1) to deep (18).

High amplitude rhythmic discharge can be recognized in the RAT electrode (in particular at 10-14 and 14-18) as well as the RPT electrode (10-11 and 14-18). In contrast, no electrographic seizure discharge is seen on the scalp recording (FP1-F7, FP2-F8).

Methods

At the Yale Epilepsy Center, the evaluation for surgical treatment of intractable epilepsy routinely includes depth electroencephalography, provided prior evaluation of the patient satisfies strict selection criteria. An epileptic patient referred to us is considered medically refractory when unacceptable seizure activity continues despite trials of all appropriate anticonvulsant drugs with documented therapeutic serum levels. It is decided then whether the patient fulfills the generally accepted initial criteria for consideration of surgical therapy as enumerated above. Specific exclusions from further evaluation include: 1) Evidence of a progressive CNS disease other than epilepsy; 2) Unstable metabolic parameters which are a possible cause of, or modifying factor in, seizure diathesis; 3) Unwillingness or inability to participate in the presurgical evaluation. There are no specific age-restricting criteria.

If the general cirteria are met, surgical evaluation at Yale proceeds in four phases as described in Table 1. The evaluation is designed to achieve as much precision as possible in the detection and definition of seizure foci. Depth electroencephalographic monitoring is done at the West Haven V.A. Medical Center where specially trained personnel and technical facilities are available. All patients initially receive a careful and detailed physical examination. An exhaustive history is taken with careful attention to supplemental information supplied by friends, family, and referring physicians. The entire evaluation procedure and methods are reviewed with the patient and family in detail.

Table 1
PHASES OF SURGICAL EVALUATION

Phase I—aims to establish scalp localization if possible, and to exclude those with EEG and clinical evidence of multifocal disease.

1. EEG baseline X 3
2. EEG overnight recording with audiovisual monitoring
3. Sleep deprivation
4. Nasopharyngeal and/or sphenoidal leads
5. Medication withdrawal if necessary

Phase II—aims to investigate for structural CNS abnormality demanding surgery, and document other localizing findings.

1. Skull films
2. CT scan
3. Pneumocephalogram
4. Cerebral angiography
5. Regional cerebral blood flow
6. CSF examination
7. Neuropsychological evaluation
8. Formal visual fields
9. Cerebral amytal test

Phase III—aims to establish definitive localization, and exclude those with multifocal disease or surgically inaccessible disease.

1. Depth electrodes implanted
2. Continuous A/V/EEG recording
3. Electrical stimulation

Phase IV—aims to resect abnormal area

1. Cortical mapping (certain patients)
2. Electrocorticography (certain patients)
3. Cortical resection
4. Pathology

Phase I of presurgical evaluation aims to establish scalp EEG localization. Patients have at least three baseline electroencephalograms with nasopharyngeal and sphenoidal leads at least once. Overnight recording of the EEG with simultaneous audiovisual monitoring is part of this evaluation. Further monitoring for many days and nights may be necessary to record a minimum of three seizures. Medication is withdrawn if seizures do not occur spontaneously. If patients have unequivocal multiple epileptogenic foci on the basis of clinical and electrical data, they are excluded from further workup at this point.

Phase II aims to further select patients for depth recording by detecting those with structural CNS abnormalities which may make them candidates for surgical intervention without further evaluation (cyst, tumor, vascular disease). Localization of an epileptogenic zone is not necessary for patients to proceed to Phase III, which involves stereotactic placement of depth electrodes in the temporal and/or frontal lobes, the exact locations being dictated by the results of prior evaluation. Continuous monitoring of the electrical activity shown by the implanted electrodes is performed and at least three spontaneous seizures are recorded for analysis of the exact site and consistency of seizure onset. Medication withdrawal may again be required.

Testing of language dominance and memory processing are performed during unilateral cerebral amytal injection. This technique, first described by Wada[38] allows the assessment of language and new learning competency of each hemisphere individually while the other is anesthetized. A failure to adequately process and retain verbal information while the hemisphere of presumed epileptogenic activity is anesthetized implies dysfunction of the contralateral hemisphere as well and argues against surgical intervention.[39] If the hemisphere of epileptogenic activity is dominant for speech, modifications in surgical procedure may be necessary.

A decision about localization of the epileptogenic focus is then based on all the information obtained. If the focus involves an area of cortex which is surgically approachable and resectable without production of an unacceptable neurological deficit and if no other foci are known to exist, surgical excision of the abnormal area is carried out with mapping of speech and motor areas as indicated.

Case Reports

The epilepsy surgery program at Yale has been in operation for 6 years. Our experience in 24 patients has shown that depth electroencephalography can indeed confirm, contradict, or add to the information obtained by scalp electroencephalography. The following case reports illustrate how unexpected information obtained from depth recording can alter surgical plans.

Case Report

Case 1. E.C., a 26-year-old, right-handed, white male with a history of febrile seizures began at age 3 having multiple seizures of the grand mal, partial elementary (focal motor) and partial complex (psychomotor) types increasing in frequency to two per week. Prior evaluation had revealed a right temporal spike focus, a left frontal spike focus, and some spontaneous seizures with clearcut onset in the right temporal lobe on the basis of scalp electroencephalography. At age 26, because of continued refractory seizures, the patient underwent placement of bilateral frontal and temporal depth electrodes. Subsequent recording documented 4 seizures beginning on the left, 2 on the right, and 2 without clearcut focal onset. It was evident that the presence of at least two independent epileptogenic foci each producing clinical seizure activity made surgical intervention inadvisable.

Case 2. X.C. is a 43-year-old, right-handed clerk who had the onset of recurrent nocturnal grand mal seizures at age 29 and who subsequently developed partial complex seizures at a frequency of one or two weekly. These continued despite trials of numerous anticonvulsant drugs. Repeated EEGs showed right or left or bitemporal slowing, a right temporal sharp wave focus, left temporal sharp activity, and right sided sharp waves from nasopharyngeal leads. Recorded seizures showed no change in scalp EEG for 10-15 seconds and then right temporal slowing without epileptiform discharge. Neuropsychological testing revealed evidence of predominantly left parietal dysfunction. In July 1978 the patient underwent implantation of bilateral anterior and right posterior temporal depth electrodes. Six recorded seizures all had their onset in the right anterior hippocampal area. On 8/21/78 right temporal lobectomy was performed. One year followup indicated excellent control with only one flurry of seizure activity associated with inadequate serum anticonvulsant levels. Thus, a patient with refractory partial complex seizures but without clearcut localization of the focus on scalp EEG was able to undergo a therapeutic surgical procedure because depth recording adequately localized the epileptogenic area.

Discussion

Our basic understanding of the mechanisms by which surgical excision of epileptogenic cortex is of benefit in epilepsy stems from the still valid tenets of Hughlings Jackson and the concept of a discharging lesion as the origin of cortical epilepsy. Clinical seizure activity results from propagation of the discharge from the "focus" of epileptic neurons to adjacent epileptic neurons until the condition is achieved whereby nearby normal cells are recruited to fire in this abnormal bursting fashion.[40] Thus, the seizure spreads through presumably normal brain and clinical epilepsy arises. If the population of epileptic neurons responsible for this recruitment process is removed in toto, a propagating clinical seizure is not initiated.

Experimental data provide impetus in the search for methods of seizure control. The phenomenon of kindling, whereby repetitive, electrical, cortical stimuli have, under experimental conditons, resulted in spontaneous seizure activity following cessation of stimulation[41 42] suggests that repetitive spontaneous discharges of epileptic foci in humans and the continual exposure of normal neuronal pools to this bursting activity have implications for the stability of these neuronal populations. How susceptible certain areas of human cortex are to such conditions is not established. Whether permanent changes can occur, and whether these changes can be of sufficient magnitude to result in modification of seizure threshold, behavioral adaptation, cognitive ability, or even in new foci of spontaneous seizure discharge, are questions as yet unanswered. However, these data suggest the need for earlier operative intervention in intractable epileptic patients.

Conclusion

Excision of epileptic foci, though of proven benefit, continues to have a 30% failure rate. Clarification of selection processes is necessary, both to decrease the failure rate by detecting inappropriate surgical candidates, and to enable the selection and treatment of greater numbers of refractory epileptic patients. Recent advances in diagnostic techniques, in particular depth electroencephalographic recording, have allowed improved selection of surgical candidates.

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Attenuated Viruses and Clinical Illness

BLAKE DANIELS PRESCOTT, M.D.

ABSTRACT—This article is a case report of an individual with a series of viral infections which are exceptionally well documented; two of these clinical illnesses are subsequent to exposure to attenuated virus-vaccines. It is of special note that this patient had a presumptively protective titer to the wild (let alone the attenuated) Rubella virus when exposed to—and later becoming clinically ill from attenuated Rubella vaccine.

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A Case Report of Exposure to Vaccinees

The following case report involves a 23-year-old female who had a series of viral infections over one year documented by titer change in addition to clinical illness. The first episode provided an opportunity for baseline titers to other viruses as well as documenting her first infection. Two of the subsequent infections were after exposure to vaccinees—resulting in clinical illness in the patient in addition to titer changes; and one of those involved attenuated Rubella in spite of the patient's having a presumptively protective titer of 1:16. This is considered of special interest both as a case report and as a comment on our present program in the state of using low Rubella titers to indicate protection from wild (and attenuated) viruses.

In January of 1978, the patient had a syndrome of nasal congestion, sore throat, headache, productive cough, myalgia, dizziness, and chills with a fever of 102.4. On examination she was noted to have a rhinitis and pharyngitis along with lymphadenopathy. At that time there was a positive titer change in Type A influenza from 8 to 32 (a 4-fold change)—documented as a 16-fold rise (none to 80) in Texas flu. This gave the opportunity to document other viral titers—particularly with regard to Rubeola and Rubella.

On March 22 of 1978 the patient was exposed to a child who had had attenuated Rubeola vaccine. Her titer to Rubeola had been established at none on February 6. On April 20 of 1978 she had a syndrome of sore throat, lymphadenopathy, productive cough, loose stools and fatigue associated with a fever of 101, swollen eyelids, and a rash. The rash was papular, centripetal, particularly marked on the face, confluent on both the face and trunk, and present on both the dorsal and palmar surface of the hands. There was also a hemorrhagic eruption over the soft palate. Viral studies at this time showed a 64-fold rise (I.E., up to 128) in titer for **Rubeola.**

The patient was then relatively well until October of that same year when she became tired and weak and complained of a cold and cough productive of bloody sputum associated with diarrhea and vomiting. No definitive etiologic agent was isolated at that time and no definitive titer change in viruses was noted.

In October of 1978 the patient developed a singular salmon-colored, oval papular lesion which subsequently had a healing center. This was followed by a generalized eruption in a "Christmas tree" distribution of similar papular lesions with a centripetal distribution. This gradually evolved over the next two months. This then cleared. This was felt to be a characteristic eruption of pityriasis rosea.

On November 15, 1978, the patient was **exposed to** a child who had been vaccinated with **attenuated Rubella vaccine.** The patient's previous Rubella titer was documented at **16** as far back as January of 1978. On November 23, the patient had a syndrome of cough productive of yellow, bloody sputum, sore throat, laryngitis, vomiting, and diarrhea, myalgia, and rhinorrhea. This was associated with a 16-fold rise in **Rubella** titer (from 16 to 256).

Interestingly enough this same young lady had thyroid tests done repeatedly with a T4 becoming slightly low (at 3.0) but with a normal T3 uptake (26) and TSH (8.9) at the time of her "Rubella syndrome" and later becoming definitively hypothyroid with a T4 of 2.4 with a TSH of 43.9.

The relationship, let alone the cause and effect, of the thyroid dysfunction can only be speculated upon. It appears, however, that the patient became definitively hypothyroid only after this series of viral infections.

It is of particular interest that a **young woman** with previous significant and **presumptively protective titer** to Rubella not only contracted Rubella with a **clinical syndrome** in association with a definitive further change in titer, but also did this after exposure to the **attenuated vaccine** in a vaccinee more than one month previous to the onset of clinical syndrome. This raises the question of our complacency in using Rubella titers as an index of protection in women of childbearing age. It is of further interest that this patient had a history of having had "measles" as a child.

A summary of the viral illnesses over one year in a 23-year-old female is presented since it affords a particularly well-documented, while unfortunate saga of this young lady in her struggle with a series of viruses during one year. While she finally developed definitive hypothyroidism, this was after a series of viral infections and no other predisposing cause to her viral infections could be elicited. Since two of these viruses were attenuated ones commonly used in vaccines, since one is related to the possibility of major malformations in the offspring of women infected while pregnant, and since this patient had a presumably protective titer prior to such exposure, this report should be of special interest to those using Rubella titers as an index of protection in young women. Whether the final hypothyroidism was caused by such a series of infections remains as moot a point as the question of a gradually unfolding hypothyroidism predisposing such a patient to these infections.

Identification of Labile Hypertension in Children of Hypertensive Parents

PHILIP WARREN, M.D. AND CHARLES FISCHBEIN, M.D.

ABSTRACT—A consecutive series of 166 children, ages five to six years received a routine Diphtheria-Tetanus booster subcutaneously as part of their pre-school examination. Resting and post injection blood pressures were recorded. Significant change was interpreted as lability and correlated statistically with parental history of hypertension.

Responsibility for the detection of primary hypertension has been given to the Pediatrician.[1] Yet, the prognostic significance of a single measurement of hypertension in children is questioned.[2]

The generally accepted recommendation remains that measurement of blood pressure in apparently normal children be performed annually after the age of three years, with the caveat that the tentative label of hypertension be placed only when elevations are sustained on repeated readings over a period of six to twelve months;[3 4] the implication of the latter being that single elevated readings may be transient, and that lability of blood pressure in children is presumed to be insignificant.

Our study involved a group of randomly selected, apparently normal and normotensive five to six year old children in our private pediatric office. Each of these children received a booster Diphtheria-Tetanus Toxoid injection as a part of their routine pre-school examination. Our purpose was to identify and quantify blood pressure lability following this mildly traumatic and anxiety producing stimulus, and to correlate the degree of lability, if any, with parental history of hypertension.

Method

Blood pressure measurements were taken during routine pre-school examination of one hundred and sixty-six consecutive, apparently healthy five to six year old children. Ninety-one were boys; seventy-five were girls. One hundred and fifty-three were Caucasian; thirteen were black. All children were examined at least one hour after lunch.

The initial blood pressure measurements were recorded at the onset of the physical examination with the patient in a supine position. The largest cuff which comfortably covered at least two-thirds of the right upper arm was used. Following the physical examination, the cuff was repositioned and a subcutaneous Diphtheria-Tetanus booster injection was administered. A second blood pressure was recorded with the patient still in the supine position. The blood pressure was measured promptly after the injection, regardless of the child's emotional state.

The purpose of the repeated blood pressure determinations was explained to the parent during the visit. After the office visit, a history of hypertension in the parents was sought and recorded.

Results

The mean systolic and diastolic pressures at rest for all patients studied in mm Hg were 92.54, and 54.27, respectively. These values are quite comparable to those reported for this age group by others.[5] Their mean systolic and diastolic pressures immediately after a subcutaneous injection of Diphtheria-Tetanus Toxoid were 96.57 and 55.76, respectively.

In the case of 119 of these children, neither parent was hypertensive. Mean systolic and diastolic pressures for these children at rest were 90.97 and 53.37, respectively. Immediately after a subcutaneous injection of Diphtheria-Tetanus Toxoid, their mean systolic pressures rose to 93.63 and their mean diastolic pressure rose to 53.88; the increments were statistically insignificant.

Hypertension was identified only in the father of eighteen of the total group of children. The mean resting systolic and diastolic pressures of these children were 94.22 and 54.44, respectively. Immediately after the injection, their mean systolic and diastolic pressures rose to 103.88 and 62.27, respectively. The difference in the increment for systolic pressure between those children with a paternal history of hypertension, and those with a negative parental history for

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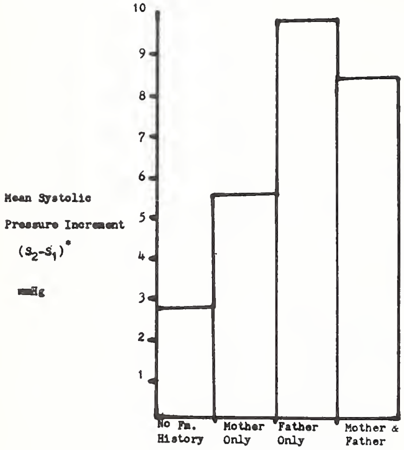
hypertension are significant by Students T test ($p=0.040$) (Figure 1) and for diastolic pressure by Students T test ($p=0.004$) (Figure 2).

Figure 1



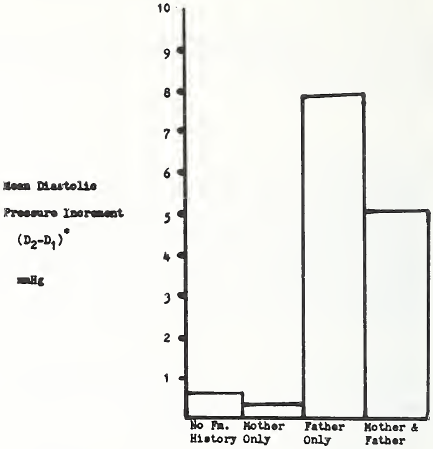
* S_1 = Initial Systolic Pressure

S_2 = Post-injection Systolic Pressure

In the case of eight children, both parents were identified as hypertensive. The mean systolic and diastolic pressures for these children at rest were 104.75 and 62.75, respectively, with a mean systolic rise to 113.00 and a mean diastolic rise to 67.75 immediately after a Diphtheria-Tetanus Toxoid injection. The difference in the increment in the systolic pressure between these children and those with a negative family history of hypertension is again significant by Students T test ($p=0.035$) (Figure 1). The difference in diastolic increment was probably significant ($p=0.06$) (Figure 2).

In the case of twenty-one children, the mothers were hypertensive while the fathers were normotensive. The mean systolic and diastolic pressures at rest for these children were 95.33 and 56.00, respectively. After the Diphtheria-Tetanus Toxoid injection, the mean systolic and diastolic pressures rose to 100.76 and 56.28, respectively. The difference in the increment of pressure between these children and those with both normotensive parents was not statistically significant, (Figure 1 and 2).

Figure 2



* D_1 = Initial Diastolic Pressure

D_2 = Post-injection Diastolic Pressure

Discussion

Our findings demonstrate a surprising constancy of blood pressure readings in most five to six year olds subjected to the moderately excitatory stimulation of a subcutaneous injection of Diphtheria-Tetanus Toxoid booster. They demonstrate further that a sub-population of these children have significantly and readily demonstrable lability of their blood pressures, and that this lability correlates statistically with a paternal history of hypertension as well as with a history of hypertension in both parents. We cannot explain, on the basis of our limited data, the apparent lack of significant correlation when only the mother is hypertensive.

It is generally accepted that adults with labile hypertension have a significantly higher risk of developing sustained hypertension than a random population.[6] This may or may not be true for those youngsters with labile hypertension identified by our technique. A prospective study of these children is underway. If this lability in children is indeed predictive for the development of sustained hypertension, then measurement of blood pressure under the conditions outlined above is a simple and important addition to the routine preschool examination. Long range clinical implications for prophylaxis, including dietary modifications and salt restriction are still tentative.[7,8]

Conclusion

A transient and statistically significant increment in systolic and diastolic blood pressure of five to six year old children following a routine Diphtheria-Tetanus Toxoid injection has been shown to correlate with parental hypertension, and especially with paternal hypertension. Larger prospective studies will be needed to demonstrate the significance, if any, of these findings.

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Glucagon Therapy of Esophageal Food Impaction

Interventional Radiology

J.J. CRONAN, M.D. AND STEPHEN STEIN, M.D.

Acute dysphagia following impaction of a food bolus in the esophagus is a medical emergency. Barium swallow is usually performed to confirm the clinical diagnosis. Current treatment with esophagoscopy and manual extraction or proteolytic enzymatic digestion risks esophageal perforation. This case demonstrates how the radiologist can offer immediate treatment with intravenous glucagon, a spasmolytic agent.

Case History

A 69-year-old white male, with a history of hiatal hernia, presented to the emergency room complaining of substernal pain and regurgitation. He had been eating an English muffin and felt the first mouthful of food lodge in his esophagus two hours before seeking help. There was a prior history of gastroesophageal reflux and occasional dysphagia.

Physical exam revealed a calm male with an upper denture. Barium swallow demonstrated a bolus impaction completely obstructing the distal esophagus (Figure 1). 1.0 mg glucagon was injected intravenously and within 45 seconds the patient reported relief of symptoms. Repeat barium swallow in the erect position showed that the bolus had passed. (Figure 2).

An antacid was prescribed and repeat swallow one week later showed a small hiatal hernia without a stricture or stenotic gastroesophageal ring.

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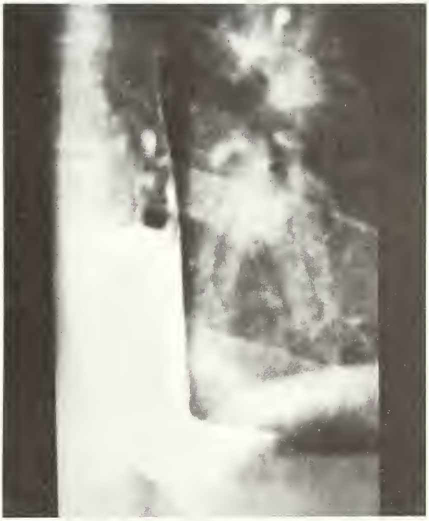

Figure 1
Food impaction obstructing distal esophagus.

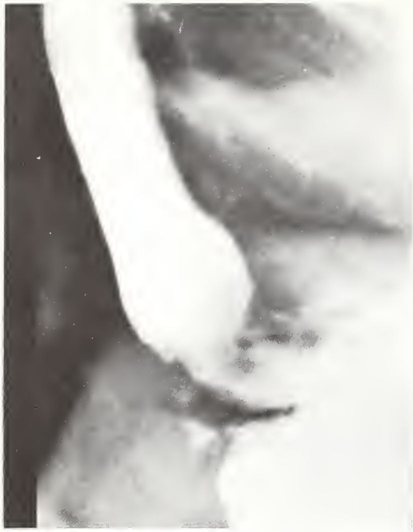

Figure 2
45 seconds following intravenous administration of glucagon food impaction has been relieved.

Discussion

Glucagon has been utilized extensively by radiologists and endoscopists to overcome colonic and small bowel peristalsis and muscle spasm during barium examination and endoscopy. Dramatic results with this spasmolytic agent are well documented.[1] The abundant smooth muscle of the lower esophagus responds readily with hypotonia. A decrease in lower esophageal sphincter pressure has also been demonstrated manometrically following administration of glucagon.[2]

The radiologist is in an ideal position to treat patients after confirming the clinical impression of acute bolus impaction.[3] Treatment using glucagon carries essentially no risk, avoids the potential complication of esophageal perforation associated with endoscopy or enzymatic digestion, and if unsuccessful can be followed immediately by the more invasive modes of therapy.

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Diffuse Histiocytic Lymphoma: A Potentially Curable Disease

GARY WITMAN, M.D. AND ED CADMAN, M.D.

ABSTRACT—Diffuse Histiocytic Lymphoma, which accounts for one-third of all non-Hodgkin's disease lymphomas, is a tumor which is potentially curative with chemotherapy. Prior to the use of adriamycin drug combinations for the treatment of this disease most patients died within nine months. These newer drug combinations have resulted in a complete remission rate of 60% with most of these patients free of disease two to five years following discontinuation of therapy. The newer immunological approaches to histopathology of this disease may eventually help identify subsets of these patients in which a more aggressive therapeutic approach would be appropriate.

Diffuse histiocytic lymphoma was, up until five years ago, a dreaded untreatable systemic illness. Recent knowledge in the area of tumor kinetics, pathology, clinical staging, and therapy have brought this malignant disease within the realm of potential curability. This article is intended to feature highlights of this recent work as well as present current approaches to clinical evaluation and treatment.

Pathology

Lymphomas are tumors primarily involving the lymph nodes. The major separation is between Hodgkin's disease and non-Hodgkin's lymphoma; both of which differ in clinical signs and symptoms, natural histories, responses to therapy, and pathological microscopy. In the past fifteen years there have been six different proposals for the classification of non-Hodgkin's lymphomas. The classification proposed by Rappaport is currently the one most commonly used.[1,2] This classification is based on the nodularity of lymph node tissue (nodular or diffuse), the degree of differentiation of the presumed malignant reticuloendothelial cells (well or poorly differentiated) and whether the predominant cell is a lymphocyte or histiocyte or a mixture of both (Table I). One-third of non-Hodgkin's lymphoma are of the diffuse histiocytic lymphoma classification (DHL); the nodular lymphocytic poorly differentiated (NLPD) classification makes up a third and the remaining subclassifications in total account for the remaining third of these lymphomas.

The normal lymph node has germinal centers, which appear as nodules or follicles, and diffusely inter-

Table I

RAPPAPORT HISTOLOGICAL CLASSIFICATION

	Abbreviations
Diffuse	
Histiocytic	DH
Mixed histiocytic lymphocytic	DM
Lymphocytic poorly differentiated	DLPD
Lymphocytic well differentiated	DLWD
Undifferentiated	DU
Nodular	
Histiocytic	NH
Mixed histiocytic lymphocytic	NM
Lymphocytic poorly differentiated	NLPD
Lymphocytic well differentiated	NLWD

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spersed cells which comprise the medulla and cortex of the node. The nodular lymphomas have an obvious follicular pattern while the diffuse lymphomas have a monotonous diffusely infiltrating cellular proliferation without follicular formation. DHL is a heterogenous tumor generally of nodal tissue in which there is a diffuse replacement of the normal architecture by cells larger than lymphocytes which have been referred to as histiocytes.

Lukes and Collins[3] have introduced a new classification for the non-Hodgkin's lymphomas which is based on immunologic principles (Table II). The foundation of this new classification is from knowledge that the follicular center cell undergoes transformation during maturation from a small cleaved to a large cleaved to a non-cleaved cell. The dividing cell of the follicular center is the large non-cleaved cell. A malignant transformation of this cell has a high proliferative rate and also the most progressive and rapidly fatal course. It is this cell that Lukes and Collins believe is the malignant cell of DHL.[3] Small and large non-cleaved follicular center cell tumors are generally diffuse on microscopy and rarely exhibit follicularity due to the rapid cell growth. The term immunoblastic sarcoma refers to a transformation of a cell which has been under chronic antigenic stimulation, as in the immune disorders rheumatoid arthritis and systemic lupus erythematosis. Plasmacytoid features are often present in some cells of the node in these situations. These cells may be the source of the occasional monoclonal protein present in these patients' serum.[3] Attempts to use this new classification to formulate clinical decisions should be resisted until adequate correlative information is obtained and a single descriptive system is adopted to guide us in these areas.[4 5]

Table II

LUKES AND COLLINS VS. RAPPAPORT CLASSIFICATION

Lymphocytic Well Differentiated, Nodular and Diffuse
- small lymphocytic (CLL)
- small cleaved

Lymphocytic Poorly Differentiated, Nodular and Diffuse
- convoluted lymphocyte
- small cleaved
- large cleaved
- small noncleaved

Mixed Lymphocytic, Histiocytic, Nodular and Diffuse
- large cleaved

Histiocytic
- immunoblastic sarcoma (T & B cell)
- large cleaved
- large noncleaved
- histiocytic

Ref: Cancer 41:303, 1978[5]

Immunochemical studies have demonstrated that many of these DHL tumors are different even from what microscopic appearance would indicate, in that surface membrane antigens and antibody receptors can be used to separate this once large group into smaller more defined sets. Generally, 50% of patients will have cells which can be characterized as B cells, while only 10% have T cell characteristics. One third of patients will have undefined membrane studies and only 5% will truly be of monocytic or histiocytic origin.[1] DHL apparently is primarily a neoplastic transformation of lymphocytes, most commonly of the B cell type, and in fact rarely derived from histiocytes.

Clinical Presentation and Staging Recommendations

The most common presenting sign of DHL is painless lymphadenopathy. Only 25% of patients have B symptoms, fever and/or night sweats, at the time of diagnosis.[6] Due to rapid cell division, the disease may present with dramatic and florid growth which can be manifest in a few days. Males tend to be affected more than females, 1.2:1. If a patient is less than 35 years old, there is a four times greater likelihood of having a diffuse rather than a nodular lymphoma.[7] However, the average age of presentation of DHL, which is 50 years, is 10-15 years older than the average presentation of Hodgkin's disease.

Table III

SITES OF LYMPH NODE INVOLVEMENT IN DHL

Paraortic	50%
Cervical	45%
Supraclavicular	40%
Inguinal	20%
Mediastinal/hilar	15%
Epitrochlear	5%

Prospective staging at the National Cancer Institute of 170 patients with non-Hodgkin's lymphoma demonstrated that 80% of patients with DHL have disease limited to the lymph nodes; the most frequent sites of extralymphatic involvement were the bone, skin, and gastrointestinal tract[8] (Table III). The purpose of extensive pretreatment staging of patients with DHL is to identify those patients with local (stage I and II) from extensive disease (stage III and IV). This distinction is important because radiation therapy can cure patients with local disease.[9] Only 5% to 7% of patients with nodular disease have stage I or stage II disease following extensive evaluation. However, 30% of patients with DHL will remain stage I or II following staging.[8 10] Therefore, it is reasonable to consider an extensive evaluation including laparotomy only for DHL patients who present with stage I or II disease in which the planned treatment is only radiation. The nodular lymphomas, conceptually, are disseminated once the diagnosis is established and the staging should be limited, certainly not to include laporatomy. The evaluation of the patient with DHL should include the following sequential evaluation (Table IV).

Table IV

SEQUENTIAL STAGING PROCEDURE FOR LYMPHOMA

History, physical exam

Serum chemistries - Electrolytes, BUN,
Creatinine, Calcium

Complete blood count, platelet count

Radiograms - CXR, bone films, lymphangiography

Sulfur colloid liver spleen scan

Gallium scan*

Bilateral posterior iliac crest bone marrow biopsy

Liver biopsy - percutaneous, peritoneoscopy*

*optional study

With computerized transaxial tomography (CT) the retroperitoneal area can easily be examined. However, it does not replace lymphangiography for the evaluation of paraortic and iliac lymph nodes. CT scanning can only demonstrate changes in the size of nodal structures but cannot define architecture, which may be more important than size in suggesting the presence of lymphoma.

Central nervous system involvement with DHL occurs in 2% of patients at the time of their initial diagnosis; generally with cranial nerve palsies or changes in mental status. The cerebral spinal fluid (CSF) will generally have excess lymphocytes and a slight elevation of protein, the glucose and opening pressure are generally normal. Mass lesions are seldom present and therefore a normal CT scan of the brain is not useful in eliminating this diagnosis in the patient with symptoms. Multiple examinations of the CSF may be necessary to accurately establish the proper diagnosis. It is of interest that nearly all patients with CSF involvement had DHL present in their bone marrow.[11]

Therapy

DHL is readily amenable to treatment with alkylating agents, antimetabolites, and drugs interfering with protein and nucleic acid synthesis, perhaps a consequence of the rapid proliferation of the malignant cell. Initial treatment regimens were empiric; recent use of cell kinetic principles have led to the rational development of effective and potentially curative programs. Radiotherapy is very effective for the treatment of local disease; 70% ten year survival in stage I disease and 30% ten year survival in combined stage II and III disease, but no ten year survivors of patients with stage IV disease.[9]

For stage IV diffuse lymphoma initial trials with oral alkylating agents, primarily cyclophosphamide, led to transient complete clinical remissions in only 10% of patients.[12] The combination chemotherapy of cyclophosphamide, vincristine and the lympholytic agent, prednisone; commonly referred to as C.V.P., only increased the complete response rate to 15%. However, the addition of adriamycin (hydroxydaunomycin) to these agents (CHOP) resulted in a dramatic increase in complete response rate between 39% and 69%.[13,14] These drugs do cause myelosuppression and disease relapse may occur during the time of bone marrow suppression. Relapse of disease is usually associated with the development of a refractory state to further treatment with the same agents, necessitating an immediate change in chemotherapy. Current pharmacokinetic studies allow the rational introduction of non-myelosuppressive agents during this period of marrow recovery.[15] Current protocols at Yale make use of prednisone, bleomycin, cytosine arabinoside (Ara-C) and high dose methotrexate with leucovorin rescue. Combinations such as A-COMA (adriamycin, cyclophosphamide, Oncovin®, methotrexate, and Ara-C) and BACOP (bleomycin, adriamycin, cyclophosphamide, Oncovin®, and prednisone) have resulted in 75% complete response rates with most patients remaining disease free from three to five years. Drugs are

Table V

STAGING

Clinical Stage

That stage of disease as determined by history, physical examination, x-rays, scans, blood and urine tests and initial biopsy results.

Pathological Stage

That stage of disease as determined after exploratory surgery and histopathology, and evaluation of liver, spleen, periaortic and mesenteric lymph nodes and bone marrow biopsy.

A and B Symptoms

A - no symptoms

B - a) unexplained weight loss of more than 10% previous body weight during preceding 6 months.

b) unexplained temperatures greater than 38°C.

c) night sweats.

E Classification - extranodal sites of disease which are contiguous with involved lymphatic structures; or an isolated extranodal site of lymphoma.

Stage

I. Involvement of a single lymph node region *or* a single extralymphatic organ or site (IE).

II. Involvement of 2 or more lymph node regions on the same side of the diaphragm, or localized involvement of extralymphatic organ or site and 1 or more lymph node regions on the same side of the diaphragm (IIE).

III. Involvement of lymph node regions on both sides of diaphragm; may also involve extranodal sites.

IV. Diffuse or disseminated involvement of 1 or more extra lymphatic organs or tissues.

Definition of Lymphatic Structures

Lymph nodes, spleen, thymus, Waldeyer's ring, appendix and Peyer's patches.

Ref: Report of the Committee on Hodgkin's Disease Staging Classifications. Cancer Res. 31:1860, 1971.[15]

given for only nine months and then stopped, providing the patient has no evidence of lymphoma. Patients who have a complete remission of their disease generally do so during the first or second month of therapy. Relapse of disease is rare in patients who remain in remission at the completion of therapy. Effective treatment however is seldom successful if the lymphoma reoccurs or begins in the central nervous system.

Prognosis

The challenge in the treatment of patients with DHL is the induction of a complete remission. Of all the non-Hodgkin's lymphomas, DHL has shown the highest relapse rate during the first year, with late reoccurrence being uncommon. Approximately 60% of patients who achieve a complete remission with the newer combination drug programs remain free of disease without further treatment for greater than thirty-six months,[13] and are considered cured of their once fatal disease. This must be contrasted to a median survival of six to nine months before these treatments were available. These results are similar to the effectiveness of combination drug therapy for Hodgkin's disease,[16] a disease also considered curable.

Prognostic factors are dependent on the achievement of a complete remission. There has been no statistically significant difference in survival between partial responders and non-responders, with the median survival being nine months. Poor prognostic factors in DHL include involvement of the liver, bone marrow, central nervous system and a tumor mass at one site greater than 10cm. The areas of lymphomatous visceral involvement responsive to chemotherapy are the skin, gastrointestinal tract, bone marrow and pleura. Hemorrhage from the bowel has occurred after aggressive combination chemotherapy, and has, in our experience, been life threatening.

Goals for the immediate future are to improve the initial induction treatment and finding methods of reducing drug induced myelosuppression, which is currently the dose limiting factor in the management of advanced disease. Future correlations will determine the clinical benefit of the immunologic classification of the lymphomas, which could identify subsets of these patients that might benefit from different therapy.

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Estrogen Use and Postmenopausal Women

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Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A Consensus Development Conference on Estrogen Use and Postmenopausal Women was held at the National Institutes of Health September 13-14, 1979. The meeting was scheduled to explore the risks and benefits of estrogen use, which are of great interest to the nation's 31 million postmenopausal women and their physicians.

Among the subjects addressed were the benefits of estrogen use, including treatment for menopausal symptoms and possible prevention of osteoporosis; hazards of estrogen use; relative risks and benefits of various types of estrogen therapy; economic issues; and indications for and contraindications to estrogen use.

At NIH, consensus development conferences bring togther biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficicy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

This summary is based on the three position papers prepared for the conference, the response of the panel, and the general discussion by the audience, followed by an analysis by the panel and other invited conference participants. All conclusions presented below represent the general consensus that was reached.

In approaching the topic, the group first reviewed the evidence for the efficacy of estrogens in treating specific conditions associated with the menopause. It was accepted that estrogens are more effective than placebo in decreasing the frequency and/or severity of vasomotor symptoms (hot flashes and sweating). The questions that remain to be answered include whether vasomotor symptoms represent a homogeneous entity with a single cause and why some patients require much larger doses than average to control symptoms. There was general agreement that the decision of whether to initiate therapy should depend on the severity of symptoms and the patient's perceived need for relief and that the lowest effective dose should be utilized. The occurrence of hot flashes naturally declines over a period of time, and unnecessary prolongation of therapy should be avoided.

It is recognized that estrogens are effective in overcoming the atrophy of the vaginal epithelium (wall) and the associated symptoms, which may include dryness, burning, itching, and pain on intercourse. It was suggested that the possible relationship

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NIH Consensus Development Conference Summary Vol. II

EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

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Brief Summary

INDICATIONS: For the prevention and treatment of nocturnal recumbency leg muscle cramps, including those associated with arthritis, diabetes, varicose veins, thrombophlebitis, arteriosclerosis, and static foot deformities.

CONTRAINDICATIONS: Because of the quinine content, Quinamm is contraindicated in women of childbearing potential, in pregnancy, in patients with known quinine sensitivity, and in patients with glucose-6-phosphate dehydrogenase deficiency. Hemolysis (with the potential for hemolytic anemia) has been associated with a G-6-PD deficiency in patients taking quinine.

PRECAUTIONS: Thrombocytopenic purpura may follow the administration of quinine in highly sensitive patients. Recovery will follow withdrawal of the medication.
Cinchona alkaloids, including quinine, have the potential to depress the hepatic enzyme system that synthesizes the vitamin K-dependent factors. The resulting hypoprothrombinemic effect may enhance the action of warfarin and other oral anticoagulants.

ADVERSE REACTIONS: Aminophylline may produce intestinal cramps in some instances, and quinine may produce symptoms of cinchonism, such as tinnitus, dizziness, and gastrointestinal disturbance. If ringing in the ears, deafness, skin rash, or visual disturbances occur, the drug should be discontinued.

DOSAGE AND ADMINISTRATION:
1 tablet upon retiring. When necessary, 1 additional tablet may be taken following the evening meal.

Product Information as of September, 1977

U.S. Patent 2,985,558

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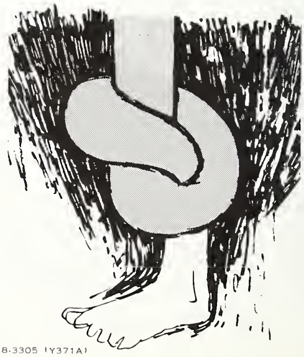

8-3305 (Y371A)

of urinary tract symptoms to estrogen lack be more thoroughly investigated. Attempts to avoid systemic effects by treating vaginal symptoms with local application of estrogen-containing creams have been common. However, evidence now exists that the estrogens in these creams may be absorbed rapidly into the bloodstream. The biological consequences of this absorption are undetermined and require study.

There is no evidence at present to justify the use of estrogens in treatment of primary psychological problems. Surveys have shown no established specific or temporal association of sleep patterns, mental performance, mood, or psychological state with menopause or estrogen deprivation. On the other hand, in preliminary intervention studies comparing estrogens to placebo, effects on sleep latency and REM sleep have been noted. Some improvement in mental well-being in women receiving estrogens may be secondary to alleviation of physical symptoms.

The group acknowledged the validity of three randomized trials indicating that exogenous estrogens can retard bone loss if given around the time of the menopause. Except for dietary calcium, which appears to decrease bone loss to a lesser extent, other substances have not been shown to have such an effect. It is inferred but not proven that this retardation of bone loss will prevent the ultimate development of osteoporosis and attendant fractures. Case-control studies not yet published but discussed at the meeting report an association of estrogen use with a decreased risk of osteoporosis-related fractures. However, more data are definitely needed before the efficacy of estrogens in preventing fractures can be established. An inconsistency was noted: namely, in the randomized trials, accelerated bone loss following discontinuation of estrogen use resulted in loss of any favorable effect on bone mass, whereas in the case-control studies, use of estrogens at any time in the past conferred some protection against fractures. Identification of patients at increased risk of osteoporosis would be desirable because of the strong possibility of successful prophylaxis. One high-risk group in which to investigate possible benefits of estrogens consists of patients who already have developed osteoporosis and sustained fractures. Estrogen administration represents a promising approach to prevention of the widespread problem of hip fracture.

There is no convincing evidence that estrogens in customary doses increase the risk of thromboembolic phenomena, stroke, or heart disease in women who have undergone natural menopause. Although it was once hoped that estrogens would protect against heart disease in aging women, this effect has not yet been demonstrated. One promising approach would be to devise a more physiological mechanism for estrogen replacement. Because oral therapy results in the delivery of supraphysiological concentrations of estrogens to the liver, it can exert an exaggerated effect on lipoprotein metabolism, blood coagulation, and other important processes.

The group then reviewed the evidence for adverse effects associated with postmenopausal estrogen use. In the absence of exogenous estrogens, the incidence rate of endometrial cancer is approximately 1 per 1,000 postmenopausal women per year. It was recognized that this rate increases several fold beginning after approximately 2 to 4 years of use of 0.625 or 1.25 mg of conjugated estrogens per day. Evidence was presented that the risk of endometrial cancer increases with the duration of use and declines after discontinuation. Estrogen use is most strongly associated with lesions of the lowest grade and earliest stage. Of interest is the temporal relationship of the number of estrogen prescriptions and the incidence of carcinoma of the endometrium: both rising steadily until 1976 and then declining in parallel. Although the incidence of carcinoma of the endometrium rose, mortality from the disease did not increase. A considerable part of this discrepancy may be attributable to early detection and the high cure rate.

Cystic hyperplasia of the endometrium, which is considered a premalignant condition, has been associated with unopposed estrogen, whether endogenous (as in anovulatory states) or exogenous. The cost effectiveness of sampling the endometrium in order to screen for endometrial hyperplasia and cancer in completely asymptomatic women currently or potentially receiving estrogens is uncertain at present. It was agreed that suction curettage is effective in evaluating the endometrium and that the cause of any bleeding must be determined. A report indicating that uterine bleeding may sometimes be absent early in the course of endometrial cancer was presented at the meeting. Hence, prudence would suggest that, even in the absence of bleeding, the endometrium should be sampled before and during estrogen therapy (on a yearly basis).

The use of progestins for several days of each estrogen treatment cycle has been demonstrated to decrease the occurrence of endometrial hyperplasia and might also reduce the associated risk of developing cancer of the endometrium. Before the application of combined therapy becomes established, risks of the various progestins must be adequately evaluated.

The association of estrogens and breast cancer in experimental animals is well known. Careful review of several well-conducted case-control studies has not revealed such a relationship in humans. In two follow-up studies of estrogen users, varying associations were encountered. Compared to data on the general population, one showed an excess of cases in years 5 to 9, but the other only after 15 years, of estrogen use. Incidence rates of breast cancer have not changed in parallel with those of estrogen use, as have those of endometrial carcinoma. Because of the high incidence and relatively poor prognosis of breast cancer, any possible association with estrogen use remains a concern.

There are experimental data indicating that estrogens can induce the production of lithogenic bile, and in one study a 2.5-fold relative risk for the development of surgically confirmed gallbladder disease was observed.

One area of general agreement was that the patient should be given as much information as possible about the evidence for the effectiveness of estrogens in treating specific menopausal conditions and the risks that their use might entail. Patients must be kept continually informed of new findings as they arise. Given the current state of knowledge, no general recommendation, applicable to all postmenopausal women, can be made.

Some concern was expressed about women who have undergone menopause many years in advance of the normally expected age. Although most of the participants felt intuitively that approximation of the normal physiological state through hormone replacement therapy would be best, there are no carefully controlled studies comparing the risks and benefits in these circumstances. Support was voiced for conserving the ovaries of young women when possible.

General consensus was reached on the current state of knowledge, as described. It is clear, however, that much additional information is needed. Specifically, we need systematic knowledge of the natural course of the menopause in the absence of hormonal therapy, of alternatives to estrogen use, of the optimal way to provide estrogens if they are to be used, and of all aspects of their beneficial and adverse effects. Special attention should be directed toward studies that can determine the proper use of estrogens in young women having undergone oophorectomy ten or more years before the natural time of menopause. No general formulation regarding therapy can be given. Rather each individual patient must base her decision on the relative values that she assigns to relief of symptoms, to expectations for optimizing health and well-being, and to various risks sustained in the process. Socially and culturally based attitudes toward the menopause may influence these values and require further definition.

Panel members and other participants who produced this summary were:

Kenneth J. Ryan, M. D., Boston Hospital for Women, Boston, Massachusetts; Elizabeth Barrett-Connor, M.D., University of California, San Diego, La Jolla, California; Daniel D. Federman, M.D., Harvard Medical School, Boston, Massachusetts; Gerald R. Gehringer, M.D., Louisiana State University Medical Center, New Orleans, Louisiana; Gerald A. Glowacki, M.D., Franklin Square Hospital, Baltimore, Maryland; Saul B. Gusberg, M.D., Mt. Sinai School of Medicine, New York, New York; Elizabeth D. Jones, M.S.W.,C.S.W., Coordinator, Women's Hormone Information Service (WHISTLE), Shelburne, Vermont; Howard L. Judd, M.D., University of California, Los Angeles, California; Stanley G. Korenman, M.D.,Veterans Administration Hospital, Sepulveda, California; Anne M. Seiden, M.D., Cook County Hospital, Chicago, Illinois; Noel S. Weiss, M.D., School of Public Health and Community Medicine, Seattle, Washington; Barbara S. Hulka, M.D., M.P.H., University of North Carolina, Chapel Hill, North Carolina; Isaac Schiff, M.D., Boston Hospital for Women, Boston, Massachusetts; Milton C. Weinstein, Ph.D., Harvard University, Cambridge, Massachusetts; and B. Lawrence Riggs, M.D., Mayo Medical School, Rochester, Minnesota.

Medicare Assignment Rate Improvement Demonstration

A Physician Reimbursement Reform Proposal

BLUE CROSS & BLUE SHIELD OF CONNECTICUT, INC.

Improvement of the Medicare Part B assignment rate through modification of the claims processing and reimbursement systems is the focus of a proposal submitted by Blue Cross & Blue Shield of Connecticut to the Health Care Financing Administration of the Department of Human Services (formerly HEW). If approved, the project will begin operations October 1, 1980 for a three-year period. The Health Care Financing Administration's response to this proposal is anticipated in early 1980.

Physicians and other health care providers who sign agreements to participate in this demonstration project will submit claims for all Medicare beneficiaries in essentially the same manner as claims for Blue Cross & Blue Shield Century Contract members. Under this voluntary agreement, participating providers would accept assignment on all Medicare Part B claims and would receive full payment of the Century Contract allowance in effect at the time. The scope of coverage for this program would include all services covered by Medicare; new allowances would be added as necessary.

The Medicare Part B annual $60 deductible will be waived for services rendered by providers participating in the program. Blue Cross & Blue Shield of Connecticut will assume responsibility for collecting the 20% coinsurance from supplemental insurers, Medicaid, and from beneficiaries not enrolled in any supplemental program. Participating Providers would have the option of waiving the coinsurance in individual cases.

Claims for services by health care providers not electing to participate in the demonstration program would continue to be processed as they are now through the Medicare carrier. Assignment would continue for those providers on a claim by claim basis and the Medicare Part B deductible would apply.

Table I
MEDICARE PART B—FACTORS RELATED TO ASSIGNMENT

	PREVELANCE OF MEDICARE CARRIER[1]	COMPARABILITY OF MEDICARE SYSTEMS				EXTENT OF PROVIDER RISK[5]
		Claims Processing		*Reimbursement*[4]		
Rhode Island	85%	Yes[2]	(7.6%)[3]	Yes	(6)	10%
Massachusetts	55	Yes	(11.7%)	Yes	(6)	20
N.H./VT.	45	Yes	(11.8%)	Yes	(5)	35
Metro N.Y.C.	45	Yes	(8.0%)	Y/N	(3)	30
Connecticut	10	No	(15.0%)	No	(1)	50

[1] percentage of non-Medicare population with basic medical/surgical coverage (estimated to nearest 5%)
[2] considering claims submission, review, and payment procedures.
[3] percentage of submitted claims denied in whole or part (FSY1979)
[4] considering methodology (0-3), data base (0-1), procedure codes (0-1), average amounts (0-1)
[5] percentage of beneficiaries *without* full supplemental coverage of cost-sharing by private insurance or Medicaid (estimated to nearest 5%)

This summary was prepared by R. Bruce Thayer, M. D., Senior Vice President, Medical & Professional Affairs, Blue Cross & Blue Shield of Connecticut, Inc. This proposal was made to HEW/HCFA in October 1979.

Table II

MEDICARE PART B—PHYSICIAN ASSIGNMENT (FSY1979)

	ASSIGNMENT RATES		ADDITIONAL BENEFICIARY LIABILITY[1]		AVERAGE REIMBURSEMENT RATIO[2]
	Covered Claims	*Covered Charges*	*$ Amount (millions)*	*% of Benefits*	
Rhode Island	80.8%	85.7%	$ 1.6	3.2%	77.6%
Massachusetts	78.2	81.9	11.2	3.7	81.5
N.H./VT.	52.2	54.3	4.0	10.1	83.5
Metro N.Y.C.	50.8	60.8	67.5	8.6	81.3
Connecticut	44.7	41.4	12.8	8.8	87.5
Other New England	74.2	79.2	18.5	4.3	81.4
All New England	68.2	69.6	31.3	5.5	82.9
Nation	51.3	50.1	1,032.8	9.9	83.3

[1] the difference between providers' non-assigned "billed" charges and Medicare's "covered" charges (N.B.-does not include applicable cost-sharing on "covered" charges)

[2] the ratio of Medicare's "covered" charges and providers' "billed" charges

Data Source: HEW/HCFA "Quarterly Report(s) on Part B Carrier Reasonable Charge and Denial Activity"

As part of the demonstration project, Blue Cross & Blue Shield of Connecticut will undertake extensive provider and beneficiary education programs. Medicare beneficiaries will be able to obtain lists of participating providers and information on the schedule of allowances for common procedures. Evaluation of the project by outside consultants will assist in the day-to-day management of the demonstration project and assess the effectiveness of the program

In reviewing Medicare Part B assignment in Connecticut our conclusions parallel those of the Connecticut State Medical Society's August 1977 report to federal and state legislators.* Data suggests that low Connecticut assignment rates, relative to neighboring states, cannot be primarily attributed to reimbursement amounts. Major problems for providers and patients with the Medicare system are that claims processing is different from the most prevalent systems, and that the billing and collection of deductible and coinsurance amounts from the patient and/or his supplemental coverage are costly, aggravating and uncertain (even with "Piggy Back"). In states where the Medicare Part B reimbursement concept and methodologies are essentially the same as for the prevalent private insurer, assignment rates are highest. (See Table I) Blue Cross & Blue Shield of Connecticut is the most prevalent health care financing organization in the state, covering about one-half of the total population. The demonstration project will provide the standard procedures for billing and payment for services rendered to Medicare beneficiaries as for private subscribers.

The current assignment rate in Connecticut is slightly above 40%, well below the 70% average of the New England states. Medicare beneficiaries bear a significant financial burden because of the low assignment rate in Connecticut. For the 12 months ending June 30, 1979 additional beneficiary liability (the difference between non-assigned billed and "covered" charges, excluding applicable cost sharing) totalled $12.8 million. Under this proposal out-of-pocket expenses should be substantially reduced. (See Table II)

The key to the success of this program is support by physicians and other health care providers. Blue Cross & Blue Shield of Connecticut will work to achieve provider support and to have in effect at the time the program begins a Century Contract fee schedule whose reimbursement levels approximate the average of those allowed by Medicare.

It is our goal to remove the administrative and reimbursement differences imposed on providers by the Medicare program—and thus the differences presented to providers by Medicare patients.

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* Report published in *Connecticut Medicine,* Nov., 1977, pp.719ff.

Increasing the Assignment Rate

Through Improved Services to Connecticut Beneficiaries and Providers

CONNECTICUT GENERAL LIFE INSURANCE COMPANY

ABSTRACT—Connecticut General has worked closely with the Connecticut State Medical Society (and especially its Peer Review Systems Committee) since the beginning of the Medicare Program to improve services to physicians and their Medicare patients. CG believes that these recommendations to HCFA build on this historic cooperation. If approved for implementation by HCFA, they should result in improved administrative services to and greater acceptance of assignments by Connecticut physicians. The ultimate beneficiary, as it should be, will be the Medicare patient.

Objective

The objective of the Connecticut General (CG) Medicare proposals is to improve services to Medicare beneficiaries and providers in order to increase the Part B assignment rate statewide in Connecticut to the maximum extent possible. The CG proposals are divided into two phases. Phase I can be accomplished within the framework of current law and regulation and would result in the maximum possible increase in statewide assignment rate. Phase II, which would require Medicare waiver, would include a study of options for modified reimbursement procedures leading to an experiment designed to further increase the assignment rate and improve CG's services to beneficiaries and providers.

Background

The Medicare Part B assignment rate in the state of Connecticut, where CG has been the Part B carrier since the inception of the Medicare Program in 1966, has always been below the national average. For fiscal year 1978, the national average was approximately 51 percent, and the assignment rate in Connecticut was about 45 percent, up from 39 percent in 1976.

Since 1974 the Medicare Bureau/HCFA and CG have been exploring specific ways of improving the assignment rate. A new DP system was implemented to speed up claims processing. It did not have any real impact on the assignment rate, but Medicare did rate CG carrier performance as improved. A more detailed study was mounted in 1976 to analyze the causes of low assignment rates and to propose actions to promote an increase. The August 12, 1977 report of the Connecticut State Medical Society was especially important to this project.

After a public hearing in Hartford, the "Committee for a Better Assignment Rate" was established in early 1977. The Committee includes representatives of the Connecticut Congressional Delegation, Department of Aging, senior citizens' organizations, Blue Cross and Blue Shield of Connecticut (BC/BS), CG and HCFA. As its name implies, the Committee was established to help improve the assignment rates within the State and has met at regular intervals over the past three years.

As reported by HCFA in April 1978, several important accomplishments have resulted, including the following:

1. A Committee-developed flyer stressing the advantages for beneficiaries where providers accept assignment.
2. Informational mailing to physicians of their

This summary was prepared by Lindsay D. Hanna, Director of Government Programs, Connecticut General Life Insurance Company, the Medicare Part B Carrier in Connecticut. This proposal was made to HEW/HCFA on December 10, 1979.

"customary charge" profiles and area "prevailing" charges to reduce uncertainty concerning Medicare reimbursement. (Also one of the CSMS recommendations.)

3. Volunteer aide workshops conducted by CG to explain the assignment process and Medicare benefits.

The Committee also laid the ground work for the so-called "piggyback" program in which CG transfers Medicare claim information to BC/BS and the Connecticut Department of Income Maintenance (DIM)—the former being the largest underwriter in the state of Med-Gap, and the latter being the state Medicaid agency. Under these arrangements, the beneficiary or provider files the Medicare Part B claim with CG which in turn transmits by a magnetic tape the pertinent claim information to BC/BS and DIM. On assigned cases, checks from both CG and BC/BS/DIM go directly to the provider; and on nonassigned claims, the checks go directly to the beneficiary. In both cases, neither the beneficiary nor the provider has to make a second filing for the supplemental coverage. This program was also one of the CSMS recommendations in its August 1977 report.

A successful program to improve the assignment rate should include service improvements for both beneficiaries and providers. CG believes the recommendations described below constitute the best approach to achieve the stated objectives, represent the efforts of a proven Part B carrier, and can be accomplished at minimum administrative and program cost.

PHASE I

Proposal: Simplify Claims Paperwork

Special attention should be devoted to simplifying Medicare paper work for the provider on the assigned claim. The following items are illustrative of the type of action which will be perceived by the provider as reducing his administrative workload:

A. Modify the Provider Summary (explanation of payments sent to provider on assigned claims) to provide a clearer description of the benefit computation and simplify provider record keeping.

B. Streamline the standard 1490 claim form to ease clerical effort in completion.

C. Furnish providers with high assigned claim volume a supply of forms preprinted with their names and addresses.

D. Distribute to all beneficiaries a new plastic card with embossed ID information. Furnish high volume assignment providers with appropriate imprint machines for use with embossed cards.

Proposal: Payment of Full Allowable Charge to Providers on Assigned Claims

CG recommends that on assigned claims, the provider should be paid 100 percent of the allowable charges.

A significant obstacle to accepting assignment, from the provider's perspective, is the administrative burden of collecting coinsurance and deductible amounts from the beneficiary. CG proposes to eliminate this administrative burden for the provider. CG would establish a repayment mechanism within currently existing systems and administrative functions to minimize added costs. Thus, providers would submit only one billing, and beneficiaries would know in advance that their liability would be determined on a fixed percentage basis of Medicare's allowable charges.

On assigned claims, CG will assume the responsibility for recovering coinsurance and deductibles from the liable third party, either Supplemental Insurers or the State Medicaid Agency (Department of Income Maintenance).

For the beneficiary, the program will insure that supplemental insurance benefits are properly claimed and promptly paid. The BC/BS "piggyback" experience has demonstrated that many beneficiaries were neglecting to file claims for supplemental insurance benefits. Thus, beneficiary satisfaction should be increased, as more physicians accept assignment, and fewer filings with less paper work are required.

Special Provisions for Joint Claims of Medicare/Medicaid

Connecticut General and the Connecticut Department of Income Maintenance (DIM) currently have an exchange of information program in operation.

Under the current program, Connecticut General enters Medicaid identification into the Medicare system if it is contained on the claim, and subsequently transfers payment data to DIM on magnetic tape. CG neither maintains Medicaid eligibility information nor pays coinsurance and deductible benefits directly. DIM then pays coinsurance and deductible amounts to the provider. Approximately 14% of CG's claims involve Medicaid and are transferred to DIM. Virtually all Medicare claims for Medicaid beneficiaries are assigned and benefits are paid directly to the provider. Providers will welcome more prompt payment of the full allowable charge, and HCFA should benefit from greater efficiencies because of the integrated process.

All or Nothing Assignment:

Connecticut General has explored and rejected the prospect of experimenting with an "all or nothing" assignment approach, under which the benefits of accepting assignment are available only to providers who take assignment 100% of the time. Under this concept, those physicians who agree to accept assignment are paid in full, with cost sharing subsequently collected by the carrier. Those who do not participate are required to collect all fees from the patient, with reimbursement made by the carriers to the beneficiary.

Connecticut General's Phase I Medicare proposals are designed to achieve as rapidly as possible statewide improvement in assignment rate. Therefore, included in Phase I is an advance 100% payment to physicians on any claims on which they will take assignment even though they may not do so all the time. We believe that this provision will result in the maximum possible increase in assignment rate without forcing physicians to make a difficult decision affecting all their patients at once.

Proposal: Compile and Publish a Special "High Volume Assignment Provider" Handbook

Connecticut General recommends a program which would include special services for physicians who accept assignment most of the time. It is clearly in the interest of the beneficiary to know in advance if his or her physician will accept assignment. If may be possible, working with the Connecticut State Medical Society (CSMS) and other third party payors in the State, particularly those who market Medi-Gap policies, to develop a list of service categories or criteria which physicians could "check off" with respect to acceptance of assignment. A special handbook would then be published and distributed to beneficiaries identifying those physicians who accept assignment all or most of the time, and in what categories of services. Inclusion of physicians' names would require their consent, and the book would have to be updated regularly.

PHASE II

Proposal: Develop Experiment for Modified Reimbursement Formulae

CG proposes to undertake an analysis jointly with HCFA, and in consultation with CSMS representatives, to develop options for reform of the present reimbursement system to achieve increased assignment rates and improved services and ultimately lower physician service costs for Medicare beneficiaries. The analysis will be tailored to the specific characteristics of Connecticut and the needs of its Medicare beneficiaries. In each of the State's four Medicare market areas, representative physician service charges (for Medicare and private insurance) will be compared. Cost of living, cost of medical practice, and per capita income indices will be developed—all from data which is readily available to Connecticut General. In addition, the Medicare assignment rate within the State will be disaggregated by geographic area and other demographic characteristics to identify special targets of opportunity for increasing the rate.

It is extremely important to consult during this analytical and experiment development process with representatives of the Connecticut State Medical Society before any changes are put in final form. The major objective of any changes in the reimbursement formulae is to increase the number of practicing physicians who will accept assignments, and reduce beneficiary financial exposure. Therefore, we will seek the cooperation of CSMS in our efforts.

A Prophecy for Medicine

The medicine of the future is beset by the pitfalls of mass production, commercialism, newspaper exploitation, the soullessness of corporations, the Deification of corporations, the conflict between group-medicine and specialization, the natural lawlessness engendered by complex regulations and regimentation, the periodic flights into mysticism to which the human mind is liable and the human tendency of patients to flock to quacks and cultists when orthodox medicine, and above all, its many specialists, fail to help or to heal.

—Fielding H. Garrison, 1929

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SPECIAL NOTICES

CURRENT CONTROVERSIES IN GASTROINTESTINAL DISEASE: MEDICAL AND SURGICAL VIEWPOINTS

March 21, 1980

UConn Health Center, Farmington, CT

The Division of Gastroenterology and Department of Surgery of the University of Connecticut School of Medicine will sponsor a postgraduate course for general surgeons, general internists, and family practitioners entitled "Current Controversies in Gastrointestinal Disease: Medical and Surgical Viewpoints" on Friday, March 21, 1980 at the University of Connecticut Health Center.

For more information, write to Ms. Joan Coleman, GI Unit, University of Connecticut Health Center, Farmington, CT 06032 or call (203) 674-3238.

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Brief Summary

INDICATION
Nausea and vomiting of pregnancy.

PRECAUTIONS
Because of potential drowsiness, Bendectin should be prescribed with caution for patients who must drive automobiles or operate machinery.
Studies in rats and rabbits have revealed no suggestion of drug-induced fetal abnormalities at doses of Bendectin up to 90 times the maximum human dose. In addition, several epidemiologic studies in women who received Bendectin during pregnancy have shown that the incidence of birth defects in their offspring is no higher than in women not taking the drug during pregnancy. Nevertheless, like all drugs considered for use during pregnancy, particularly during the first trimester, Bendectin should be used only when clearly needed.

ADVERSE REACTIONS
The adverse reactions that may occur are those of the individual ingredients. Doxylamine succinate may cause drowsiness, vertigo, nervousness, epigastric pain, headache, palpitation, diarrhea, disorientation, or irritability.
Pyridoxine hydrochloride is a vitamin that is generally recognized as having no adverse effects.

DOSAGE AND ADMINISTRATION
2 Bendectin tablets at bedtime. In severe cases or when nausea occurs during the day: 1 additional Bendectin tablet in the morning and another in midafternoon.

Product Information as of January, 1978

References:
1. Meyer, C.: American Folk Medicine. Scarborough, New York, Plum Books — New American Library, 1975, p. 208.
2. Data on file, MERRELL-NATIONAL LABORATORIES
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Seventy-Five Years of American Medical Education: Perceptions and Reflections

C.H. WILLIAM RUHE, M.D.

The theme of this, the 75th Congress on Medical Education, is Medicine: A Global Discipline. The theme was chosen deliberately to remind all of us that we are engaged in education for medicine, a profession which knows no geographic or political boundaries. This afternoon we will honor outstanding medical educators from a number of other countries. On subsequent days of the Congress, we will hear from them concerning medical education in their countries.

We in the United States owe a great debt to many other nations for the heritage they have provided us. In U.S. medical education the greatest early influence came from European countries, but in recent years we have enjoyed exchange of people and ideas with almost every country on the globe. I do not anticipate that this will change in future years.

The scientific literature is, and always has been, international in scope. Recently the *Journal of the American Medical Association* has begun publication of editions in the Spanish and Portugese languages, and plans are in progress for editions in the Japanese and French languages. Many medical textbooks are available in multiple language editions. And it is only a matter of time until educational programs of all kinds are packaged for self-instructional use in many languages. Modern communications technology, including the use of satellite transmissions, will make it much easier to effect exchange of educational programs, particularly at the level of continuing medical education. A portion of the program will deal with new developments in this technology. There is probably nothing which can be done that will advance more quickly the level of medical knowledge throughout the world.

I am not thinking only of educational programs sent from the United States to other countries. International medical education is not a one-way street. The physicians of all nations can benefit from the experiences of those of all other nations, whether classified as underdeveloped, developing or fully developed. The discipline of medicine is indeed global in scope, and we can all learn from each other, on any part of the globe.

This convocation marks the beginning of the 75th Congress on Medical Education, sponsored originally by the AMA Council on Medical Education, and in more recent years jointly by the Council, the Federation of State Medical Boards, the Association for Hospital Medical Education and the AMA Section on Medical Schools, Resident Physician Section and Student Business Section. The proceedings of most of the past assemblies have been recorded, beginning with the first one, held on May 6, 1905. It is fascinating to go over the programs of past Congresses and to read the proceedings of many, as I did in preparation for this present assignment.

I can assure you of one thing, that every possible subject known to man has been considered before. I am convinced that it is impossible to develop a new program. Everything which possibly could be conceived of has been presented previously and many subjects have been presented many times. To some of you this will be depressing, to others reassuring. To me it is simply a fact of life. The basic subjects are the same. The problems are remarkably similar and they are mostly of our own making. Only the times, the places, the people and the circumstances are different.

I do not mean to imply that the entire history of medical education has been written in 75 years. That is not true even for medical education in the U.S., and our guests from other countries with much longer experience than our own would regard 75 years as a

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C.H. WILLIAM RUHE, M.D., Senior Vice President American Medical Association; Presented at the Convocation of the 75th Congress on Medical Education Washington, D.C., May 9, 1979.

very short period of history indeed. Later today we will present a Certificate in Recognition of the *250th* Anniversary of the Royal Infirmary of Edinburgh! But for us in the U.S.A., 75 years is a long time. More significant is the fact that the period of the past 75 years has been a particularly important period, the era of modern medical education in the United States, during which some order and direction have been brought about.

I will not recite a complete chronological account of all of the events which have transpired in the past 75 years. Impressions to the contrary notwithstanding, I have not been on the scene for the entire 75 year period! Let me say simply that the Council on Medical Education has been involved every step of the way in the growth and development of medical education in this country. The items selected exemplify some of the major milestones.

1. The Council on Medical Education was established a permanent standing committee of the AMA in 1904.
2. The first national conference on medical education was held in 1905.
3. The first survey of U.S. medical schools was carried out in 1906-1907, with every school being visited by a member of the Council and/or the secretary.
4. The first report on the medical schools, and their classification as A—acceptable, B—borderline, or C—unacceptable, was made by the Council in 1907.
5. The Council in 1908 requested the Carnegie Foundation for the Advancement of Teaching to carry out an independent study of U.S. medical schools. The study was made by Abraham Flexner, who was accompanied on all of his medical school visits by Nathan Colwell, the Council Secretary. The Flexner study was carried out in 1909-10 and the Flexner Report was published in 1910.
6. As a follow-up to the Flexner Report, the Council carried out a third inspection of all of the medical schools in 1911 and thereafter instituted a regular, periodic review of all schools under a formal approval or accreditation system.
7. The first survey of hospitals for the training of interns was carried out by the Council in 1912 and the first list of approved internships was published in 1914.
8. The first Essentials of Approved Internships was established by the Council in 1919.
9. In 1920 the Council established 15 committees of nine members each to study and recommend the preparation necessary "to secure expertness in each of the specialties." These committees were the precursors of most of today's specialty boards.
10. Basic standards for specialty training were developed by the Council and approved by the AMA House of Delegates in 1923.
11. The Council published the first list of approved residency programs in 1927. The Essentials of Approved Residencies and Fellowships were established in 1928.
12. The Council was authorized by the AMA House of Delegates to approve specialty boards in 1933, and adopted in 1934 the Essentials for Approved Examining Boards in Specialties.
13. Essentials were developed and an accreditation system effected for allied health professionals in physical therapy and clinical laboratory technology in 1936, for occupational therapy in 1939, for medical record library science in 1943 and ultimately in 20 additional allied health occupations.
14. Residency review committees were established, with Council representatives on each, beginning with internal medicine in 1939 and ultimately in all other specialty fields in which there is a certifying board.
15. In 1942, the Council invited the Association of American Medical Colleges to join with it in the accreditation of U.S. and Canadian medical schools through the Liaison Committee on Medical Education. The LCME has been recognized as the accrediting body since that time.
16. In 1948, the Council joined with the Advisory Board for Medical Specialties to establish the Liaison Committee for Specialty Boards for the recognition of new examining boards in the medical specialties.
17. In 1954, the Council established the internship Review Committee for the review and accreditation of internships.
18. In 1952-55, the Council carried out the first complete survey *of* and published a report *on* Postgraduate (Continuing) Medical Education in the United States (Vollan Report).
19. In 1962, the Council requested the establishment by the AMA Board of Trustees of the Citizens Commission on Graduate Medical Education (Millis Commission) which issued its report, "The Graduate Education of Physicians" in 1966.
20. In 1964, the Council established the Ad Hoc Committee on Education for Family Practice (Willard Committee) which issued its report, "Meeting the Challenge of Family Practice" in 1966. The Willard Report contained the blueprint for modern family practice residency programs.
21. In 1964, the Council established the system of

accreditation for continuing medical education in the United States.

22. In 1968, the Council invited representatives of four other major medical organizations to discuss implementation of certain recommendations of the Millis Report. These discussions led in 1972 to the establishment of the Coordinating Council on Medical Education and its related Liaison Committee on Graduate Medical Education and Liaison Committee on Continuing Medical Education.
23. In 1969, the Council requested the National Commission on Accrediting and the Association of Schools of Allied Health Professions to join with it in sponsoring the Study of Accreditation of Selected Health Educational Programs (SASHEP Study). The SASHEP Study was published in 1972 and led to the establishment in 1976 of the Commission on Allied Health Education and Accreditation (CAHEA), the Committee of the Council through which the accreditation of allied health education is now carried out.
24. In 1971 and 1978, the Council prepared and the AMA House of Delegates approved two major reports on Physician Manpower and Medical Education.
25. In 1979, the Council is engaged in the development of a major report on the status of modern medical education in the United States.

These are only highlights of the Council's activities in medical education. They do not reflect the steady, consistent, year-in and year-out attention to the multiple and detailed problems resulting from the growing size and complexity of the field.

There is no intent to imply that all of these things have been done singlehandedly. On the contrary, it has always been the Council's method to involve anybody and everybody in the planning and decision-making process who had interest and involvement in the subject at hand. The result has been an array of liaison groups and organizations which seems confusing to the casual observer and at times even to those involved in the activities. The Council on Medical Education has been the one place where everything has come together in some kind of rational relationship. Ironically, and sadly, in some instances the guests, invited to participate in a new activity, have sought to dispossess or discredit their AMA host, not knowing or caring how they came to be there in the first place. How sharper than a serpent's tooth!

The initial efforts at establishing standards were relatively primitive since conditions were so bad. As time went on and as the growth of knowledge continued, it became necessary gradually to expand both the length of instruction and the depth of the curriculum. Not only was the four-year program of medical education itself intensified and made much more rigorous, but there was also strengthening and lengthening of the period of pre-medical preparation and the addition of clinical training after the awarding of the M.D. degree. Over the years the period of internship and residency training gradually lengthened and became consolidated under the heading of graduate medical education. In the early years of the century the practice of a specialty came about through apprentice-type training of a young physician by an older physician or by gradual limitation of practice in a particular field by an individual physician. As the growth of knowledge proceeded, however, and as it became possible to identify more clearly the body of knowledge upon which to base specialty practice, apprentice-type preparation for specialty practice was replaced by formal residency programs. Today virtually every graduate embarks promptly upon formal residency training upon the completion of the undergraduate curriculum.

Graduate medical education was also intertwined with continuing medical education for many years since much of both was reparative in nature or designed for "quick and dirty" preparation of the graduate physician for specialty practice. As graduate medical education became more formalized through the growth of residency programs, however, and as increasingly improved undergraduate medical education became the rule through the implementation of the accreditation process, the field of continuing medical education gradually emerged as a separate entity, consisting of education designed to refresh knowledge obtained in earlier more formal educational periods and education designed to bring practitioners up-to-date with modern advances in scientific knowledge. This entire process has been well described in the history of the Council on Medical Education and in an article by Glen Shepherd concerning the emergence of continuing medical education as a separate field after 1938.

Review of the minutes of the meetings of the Council on Medical Education shows how the time and attention of the Council has gradually been lengthened and broadened to encompass additional components of the total educational program. Initially devoted almost entirely to the program of medical schools and undergraduate medical education, the attention of the Council began to turn to internships in the teens and to residency training in the twenties. Continuing medical education became a subject of some importance after World War II but was not given full attention until a system of accreditation for continuing medical education was developed in the 1960's.

In overall perspective one might say that the first 25 years of the century were devoted primarily to undergraduate medical education. During the second 25 years graduate medical education gradually emerged as a full partner and during the third 25 years continuing medical education appeared on the scene and has occupied increasing attention. Simultaneously, during the latter half of the 75 year period the field of allied health education has increasingly occupied the time and attention of the Council on Medical Education.

When one observes the evolutionary progression of these separate but related levels of medical education and observes that graduate medical education came marching along about 25 years after undergraduate and that continuing education came along a generation later, some of the reasons for the relative levels of difficulty in these separate areas of education became more apparent. All three levels are still evolving but the rate of change is much faster in continuing medical education because it is the newest and least well-defined area. Similarly the field of graduate medical education is still evolving and changing more extensively than that of undergraduate medical education which by now is fairly well established and standardized. It is important to realize these differences since they are inevitable results of growth of knowledge and we should be able to understand better what is happening and what night be expected to happen in each field.

It is common to speak of the "chaotic" condition of continuing medical education. Those who view this with alarm and would attempt to set things in order immediately should understand that a certain amount of time is required for maturation and definition of a new component of the total lifetime learning of the physician. To put it another way, we might say that continuing medical education today is about where undergraduate medical education was in 1925 or where graduate medical education was in 1950. Quick resolution of all of the problems and standardization of all of the activity is not only impossible but also undesirable at this stage in the evolution of the field.

We often expect too much from education and from accreditation. We can not *guarantee* competence in practice through education or accreditation or certification. All that we can do is to aim the student and the graduate in the right direction. Whether he or she achieves and maintains competence is ultimately the responsibility of the individual.

The fact that the Council on Medical Education has lived and dealt with all of these matters through the years gives it a perspective which no other group enjoys. It has been the combination of the Council's expertise and continued attention to all areas of medical education and many areas of allied health education, and the willingness of the American Medical Association to finance the establishment and maintenance of the accreditation system in the public interest, that has provided the stability and perspective necessary to insure balance and direction in the maturation of medical education in the United States. Many individuals and many organizations have contributed brilliantly, but in 75 years there has been only one common denominator—the American Medical Association through its Council on Medical Education.

In 75 years we have moved from a system of no regulation of educational standards to one approaching over-regulation—from no accreditation system to one which is beginning to weigh heavily upon institutions. Furthermore, accreditation of institutions and educational programs has been accompanied by certification of individuals and both have been and are increasingly being used by governmental bodies for the purpose of granting or withholding privileges.

In our society, it is an aphorism that law follows custom, rather than the reverse. This has certainly been true in reference to standards for medical education, where the voluntary accreditation system developed by the profession has been recognized in both state and federal law. This has been a mixed blessing. On the one hand, it has related eligibility for licensure to practice to the completion of education in accredited institutions and programs. On the other hand it has resulted in increasing demands by both state and federal governments for justification of the system, and attempts to use the system to control numbers of physicians or to effect social change.

Where is accreditation going? It is obvious that it has become progressively more complex and more costly, both for the accreditor and the accredited. When the Council on Medical Education began its survey and review process in 1904, and the first report was made at the first Congress in 1905, the measurements were gross and the process was simple. Since things were so bad in U.S. medical education, it was relatively easy to identify deficiencies—or to put it another way, it did not take much to obtain a satisfactory rating.

Over the years, as the inadequate schools disappeared, the accreditation standards became higher and the process of review more detailed. The most significant change in medical education has been its increasing length and complexity, which in turn have been due to growth of medical knowledge throughout the world. With the growth of knowledge, specialization is inevitable. And as more is learned about each and every medical specialty, subspecialization is inevitable. This is true particularly where special technics and procedures are developed. Inevitably the training lengthens, becoming narrow and deeper and more individualized, the more splintered the more splendid in the minds of many.

How far should accreditation follow? Is it necessary, or desirable, to establish special training programs—residencies or fellowships—for each narrow segment? If so, is it necessary, or desirable, to develop standards, establish review committees, carry out surveys, and accredit each segment?

We are arriving at the point where such decisions will have to be made. The reasons are simple: time, people and costs. The process of accreditation of residency programs becomes more complex, more time-consuming, and more expensive every year. It is high time that the process be examined critically.

It is probably a blessing in disguise that exigencies force this basic review. For we have probably pushed accreditation not only beyond its point of cost effectiveness but also beyond its pedagogical justification. Subspecialty residencies and fellowships have become so personalized and individualized that they have come to resemble Ph.D. programs. We have never attempted to accredit Ph.D. programs beyond determining whether qualified faculty, a satisfactory environment and an acceptable administrative structure are present at the institution offering the programs. It is my belief that we should consider a similar system for subspecialty residencies and fellowships, determining only whether the faculty, the resources and the structure are on hand. If special credentials are needed for the individuals who engage in such training, let these be earned through specialty board examinations or simply through certificates or diplomas issued by the institution or the program director.

There are many other problems which face medical education in the coming years. Is the medical education system truly responsive to the needs of society, in this country and in other countries? How will the growing costs be met for increasingly sophisticated educational programs? How many and what kinds of physicians do we need, in the U.S.A. and in the world? How many physicians can society afford? How much research is necessary to provide the ideal climate for learning? Is there an ideal curriculum? Or, even more fundamentally, what is the purpose of the medical school?

There will be no lack of questions to confront all of us, and no lack of subects for the Congress on Medical Education for the next 75 years. I do not expect to survive the next 75, but I do plan to be around for the next 25, if only to see how things are at the time of the 100th Congress on Medical Education. I look forward to seing all of you at that time!

Florida Court Refuses to Reinstate M.D. to Medical Staff

Upholding a trial court ruling, the Florida appellate court has refused to grant an injunction restoring a physician to membership on a hospital medical staff. The physician-plaintiff in *Britton vs. Humphreys Memorial Hospital* had asked to be allowed to withdraw from the staff voluntarily after his privileges were suspended. He also asked that the State Board of Medical Examiners take jurisdiction in his case under Florida's "Sick Doctor Act." The physician was allowed to withdraw from the staff voluntarily, with the understanding that he could return to the staff only when he could demonstrate that he was able to resume his practice.

Alleging that he had been denied due process of law, the physician subsequently sought a permanent injunction and damages and asked that the hospital be held in contempt of court for its actions. The trial court denied injunctive relief or damages.

In upholding this decision, the appellate court noted that the physician's withdrawal from the staff had been voluntary and observed that hospitals had latitude in setting standards of proficiency above those required for licensing. The court further held that the hospital had afforded the physician due process of law in all proceedings, as required by hospital and medical staff by-laws.

—*AMA Impaired Physician Newsletter,* Dec., 1979

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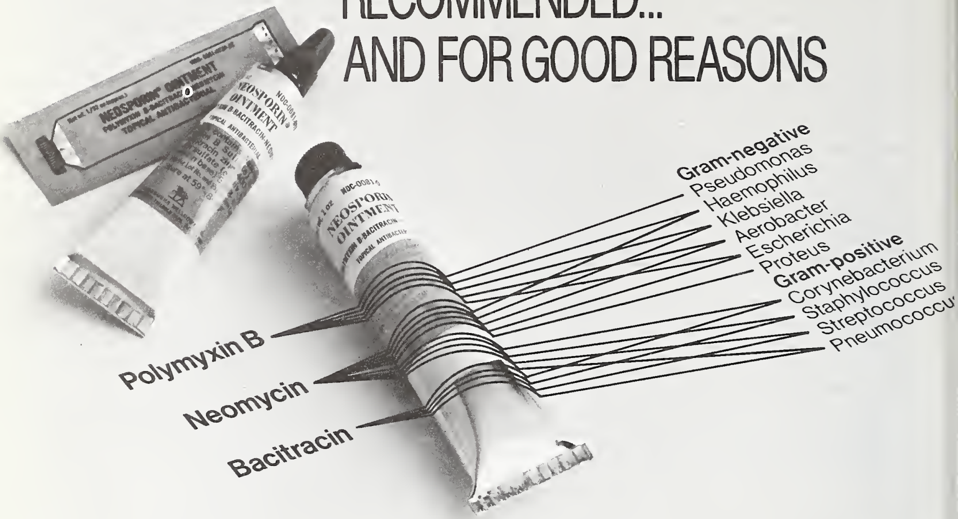

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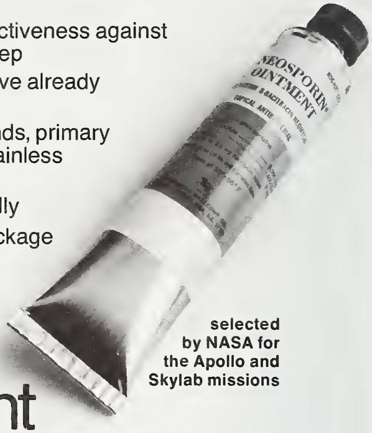

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The Consensus Development Program at the National Institutes of Health

SEYMOUR PERRY, M.D.

A young woman discovers a small lump in her right breast. Her physician, after careful examination, concludes that a biopsy should be performed. Should a two-stage procedure be used if a malignancy is discovered?

A 37-year-old woman becomes pregnant. Would it be wise to have her undergo amniocentesis to check for possible chromosomal abnormalities in the fetus?

An outbreak of an influenza A strain virus strikes a community. Should the elderly patients in a local nursing home be given amantadine hydrochloride (Symmetrel) in the prophylaxis of this type virus?

These are examples of the difficult questions addressed by consensus development panels convened by the National Institutes of Health over the past two years. These conferences bring together biomedical research scientists, practitioners, consumers and others as appropriate to examine the scientific data base in an effort to determine if there is general agreement on the safety and efficacy of a medical technology. By definition, the term "technology" is interpreted to include drugs, devices, and medical, dental, and surgical procedures which may be newly emerging or may have been widely practiced for some time.

Technologies qualify as candidates for evaluation when they have generated controversy and their use or potential use has raised some serious concerns or, if newly emerging, appear to have important implications in medical care.

With regard to the three questions posed earlier in this article, NIH consensus development panels drew the following conclusions:

- A panel considering the treatment of primary breast cancer recommended that "a two-step procedure should be done in most cases, i.e., a diagnostic biopsy should be studied by permanent histologic sections before definitive therapeutic alternatives are discussed with the patient."
- A panel addressing antenatal diagnosis recommended that "any pregnant woman age 35 or older should be advised about the possibility of undergoing amniocentesis (for detection of chromosomal abnormalities in the fetus.)" The testing was urged due to the escalating risk of delivering children with abnormalities after the mother reaches age 35.
- A panel considering the role of amantadine in the prevention and treatment of influenza concluded that if there is an outbreak of A-strain influenza, among the high risk groups who would benefit from prophylactic administration of amantadine are elderly patients in "semi-closed" institutional environments (such as nursing homes) who have not been vaccinated.

Why was the NIH consensus development program established to address such questions?

During the past 30 years great advances have been made in medical care in the United States and with these improvements has come a rapid expansion of the role of science and technology in medicine. Each year increasing numbers of new, preventive, diagnostic, and therapeutic technologies are transferred from research and development into practice.

An important element in this transfer process is the clinical trial. A properly designed and well-conducted clinical trial can lead to the validation of a new, superior medical intervention or bring into question the efficacy of an established procedure. As with other research findings, the results of clinical trials reach the practicing community in various ways—through publication in medical journals, professional meetings, seminars, continuing education programs, and control and demonstration activities.

While all these pathways serve to help physicians maintain currency, they do not in general provide them with the opportunity to assess the degree to which a given technology has been validated for safety and efficacy.

In the past, there was no formal mechanism within the biomedical research community to ensure that findings had been systematically identified and evaluated to determine if they were suitable for introduction into practice.

While biomedical research and technical innovation have led to many important advances in medicine, serious questions have arisen concerning the use of certain technologies. Critics have claimed that some technologies (e.g. tonsillectomy) have been widely adopted by practitioners without sufficient information about potential risks, benefits, cost-effectiveness, and side effects on society. At the same time, others have maintained that a number of well-validated technologies—amniocentesis, for example—have been too

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SEYMOUR PERRY, M.D., former Associate Director, Medical Applications of Research, Office of the Director, NIH; and now Director, National Center for Health Care Technology, Office of the Assistant Secretary for Health, Department of Health, Education, and Welfare.

slow in reaching the health care delivery system.

Against this background, NIH recognized that as the nation's principal health research agency it should assume the responsibility of improving the translation of research findings into practice. Therefore, in September 1977 NIH put into place a program aimed at improving the translation of the results of biomedical research pertinent to health care into knowledge that could be used effectively in the practice of medicine and in public health. The program is called "technical consensus development." A key element of this effort is the consensus development conference.

To date, more than two dozen consensus development conferences have been held on a wide variety of topics. Some of the topics discussed have included; alternatives to radical mastectomy in early breast cancer; treatment for terminally ill patients suffering from intractable pain; surgery for morbid obesity; and the removal of third molars.

The NIH consensus development program supplements but does not replace the usual methods of reporting research results in the medical literature. The results of consensus development conferences are disseminated in the form of summaries developed by conference panelists at the end of each meeting. These accounts are then widely distributed through direct mailings and publication in major medical journals and in the public media.

The Office for Medical Applications of Research (OMAR), located in the Office of the Director, NIH, coordinates and facilitates the consensus development effort and it also monitors and evaluates the program's progress. In addition to working closely with the NIH institutes, bureaus, and divisions which sponsor consensus development meetings, OMAR provides a vital link between the NIH technology assessment activities and the new National Center for Health Care Technology (NCHCT).

The NCHCT, legislatively mandated as a part of the DHEW Office of the Assistant Secretary for Health, is responsible for broadly-based technology assessments. That is, while OMAR focuses on the technical aspects of an assessment, the NCHCT is concerned with all aspects, including economic and ethical considerations, social impacts, etc. The Center also coordinates all the DHEW technology assessment activities and provides a forum in the Department when technology-related issues are surfaced and addressed. The NCHCT works closely with the congressional Office of Technology Assessment and other offices engaged in technology assessment activities to assure that unnecessary duplication does not occur.

In this program of seeking consensus on health care technologies, the Federal Government is not directly involved with the panel's deliberations, but it serves, through the NIH, as the catalyst and provides the resources for these activities. Complete and broad participation by a wide range of experts and lay persons constitutes a critical part of the overall consensus development effort. It is essential that the opportunity is provided for exploring all sides of an issue, and panel members are encouraged to include significant minority viewpoints in summary reports. This is essential because the majority view may not always be the correct one. In any event, one of the main objectives of the program is to provide the best current knowledge about medical technologies pertinent to health care by those who are in the best position to know.

The consensus development program recognizes that technologies are ever-changing and that no consensus development report should be chiseled in marble. The aim is to provide the most accurate, current information to guide those who might find use for this data—the practicing and research communities, the public, third party payers, and others. The so-called "information explosion" is recent times in all technical fields—including medicine—makes it imperative that the physician be made aware of the scientific basis for and the best thinking on a given technology.

In addition to reporting all sides of a question, the reporting of a failure to reach consensus on some issues can also prove to be valuable. This usually indicates a deficiency in knowledge about a technology and that more studies are needed.

An important aspect of consensus development conferences is that time is routinely set aside for open public discussion, by both experts and laymen. At the end of the conferences the deliberations of the panelists and the contributions by members of the audience are reflected in the final consensus documents.

Consensus development meetings differ from standard, state-of-the-art sessions in that consensus development panels have a specific charge to address the key issues and questions concerning the technology under discussion. Typically, the issues and questions are identified by expert conference planning groups, although additional concerns may surface during the course of the meeting.

The value of consensus development conference summary documents is that they force participants to examine critically the scientific/medical basis for a given technology. It constitutes an exercise to which the individual practitioner has neither the time nor the resources to contribute.

While the formats may change and the subjects may bring together different audiences in the third year of the NIH consensus development program, meetings will continue to share the same goal: to supply the most accurate, useful information to practicing physicians and biomedical scientists as well as the general public.

It is important that the medical profession continue to be supplied with this information if society is to receive the best possible health care within the constraints of available resources.

Release of Medical Records

HOUSTON PUTNAM LOWRY

Introduction

A great deal of confusion currently exists about the confidentiality of medical records. Even though this area has a number of statutes governing it, the confusion persists. Part of it may be due to an honest paranoia, which may even be healthy in this age of automated data bases. The other part of it is due to political maneuverings, where the issue is used as a political club. Whatever the reason, there is a strong surge of interest in a right to privacy. Whether the trend is growing awareness or simply a cyclical fad, it is currently a problem to be reckoned with.

Some statutes are definitely inapplicable. The Administrative Procedures Act,[1] Freedom of Information Act,[2] and Privacy Act of 1974[3] need not be followed because they apply only to governmental agencies.[4] A private hospital, such as Saint Francis Hospital and Medical Center, need not follow them. The records are not government property nor are they subject to significant government control. Merely because the hospital receives government monies is immaterial. All monies are received because the patient assigns his benefits to the hospital in order to pay his bill. The hospital is acting for its own benefit, not for the government's benefit. The hospital has no independent authority at law to perform any specific government functions. Mere government access or reliance on the records in question is insufficient to demonstrate an agency's existence. Receipt of Hill-Burton Funds in and of itself is insufficient.[5] The only time this issue has come before the courts of this jurisdiction, it was held that a private hospital is not a government agency.[6]

Eliminating these three statutes removes the bulk of restrictions on releasing information. This relative freedom should not be expected to last forever. Two bills are currently pending before the United States Congress[7] which will impose restrictions on all hospitals through commerce clause jurisdiction.[8] For the most part, a private hospital may currently do pretty much as it sees fit.

Access by Patient

A patient may access his medical record. Although a small number of court cases do exist,[9] Connecticut does have statutory law directly on point.[10] The most common and general statute is Conn. Gen. Stat. § 4-104. That governs all records, regardless of content. Once a patient makes demand on the hospital after receiving treatment and being discharged, the patient may review his record. A patient who has not been treated has no right to see his record. A patient who has not been discharged has no right to see his record. Access can either be by the patient himself, his physician, or his attorney. Ultimately, the right of access belongs to the patient.

One interesting point does appear here. A patient may inspect his history, bedside notes, charts, pictures, and plates. Yet, a patient need only be allowed to copy his history, bedside notes, and charts. Apparently a patient has no right to copy his pictures and plates, although he may view them. Yet, Conn. Gen. Stat. § 4-105 allows a judge to compel production of everything. There is no provision for penalizing a hospital that forces a patient to secure his records by court order. It is very important to note that a doctor does not have any veto power over whether or not the patient can see his record.

The same section governs production of medical records by subpoena.[11] At the hospital's option, either the original or a copy of the medical record can be delivered to the clerk of the court. Nothing can force the hospital into sending the original instead of a copy, since this choice has been vested by law into the hospital's discretion. For J.C.A.H. purposes, it would be best if only a copy is sent out and not the original.

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This article does not give legal advice. See your attorney for legal advice on your specific situation.

The record itself need only be delivered to the clerk of the court; there is no indication it need be hand carried. Use of the mails should constitute a constructive delivery, within the meaning of the statute.

Psychiatric records are also governed by Conn. Gen. Stat. § 17-206i(b). Under this section, a patient[12] has a right to inspect all of a patient's records once a written request has been made if the request is in connection with any litigation related to the hospitalization. Follwing discharge, a patient may request in writing to see his own records even though there is no litigation connected or related to the hospitalization. Under that condition, access can be denied for certain reasons.[13] Of course, a patient may still petition the superior court for relief. What effect this new revision will have, if any, is debatable. Supposedly, this new section is not intended to limit access under Conn. Gen. Stat. § 4-104.[14] Yet, a patient has unlimited access under that section once they are discharged. The restrictions only apply under the new law when the patient has been discharged and the information is not for the purposes of litigation. In short, there is an apparent contradiction.[15] It should be resolved in favour of disclosure, considering the underlying philosophies of the two sections.

In short, a patient has a right to see his medical record. This right has been found in the common law and been codified into Connecticut's statutory law. There is no requirement that either the inspection or the making of copies shall be free.[16] If the cost is placed too high, courts may hold that constructively denies a patient access to his record. In this light, the price should be reasonable.[17]

Information That Can Be Disclosed to Persons Other Than the Patient Without Consent

Very little information can be disclosed to persons other than the patient without patient consent. No information may be disclosed at all if the patient has forbidden disclosure. It is up to the patient to express his disapproval of even the most general information to the hospital. Until the patient does so, the hospital is under no obligation to withhold all information.

The hospital may disclose a patient's name and the fact the patient was hospitalized. Admitting date, discharge date, and the patient's general condition may also be disclosed. A patient may prevent the disclosure of even this general information by informing the hospital that he objects to it. It is the patient's responsibility to communicate this desire to the hospital. The patient's room number should only be disclosed while the patient is in house and the requesting party is here to visit. Otherwise, an enterprising sleuth could figure out the general nature of the patient's illness, such as the psych ward or the delivery room. Likewise, the address, phone number, attending physician, marital status, age, and religion of the patient should not be disclosed. A doctor's specialty is generally known as a matter of public record. That will give a substantial clue as to the patient's ailment. Suppose the attending physician is in only obstetrics and the patient is single. To release such information lets the public know that the woman is having an illegitimate child. Similar career damage can be done by disclosing the fact the attending physician is a psychiatrist. Therefore, as little information as possible should be given out.

Consent is not required for disclosure of psychiatric communications under certain conditions.[18] The first two exceptions involve determinations by the patient's psychiatrist, so the hospital need not be concerned with them directly. A notice of disclosure must be given to the patient when his records are disclosed in furtherance of his treatment. That is about the maximum extent of the hospital's possible involvement under these two exceptions.

The third and most relevant exception involves disclosing the name, address, and fees for psychiatric services to those involved in the collection of fees for such services. If a dispute arises only limited information can be disclosed.[19] However, the entire problem can be circumvented if the patient's consent is obtained, which it usually is.

Finally, the fourth and fifth exceptions deal with court cases such as appointing conservator by the probate court or when the patient introduces his mental condition as an element of his defense. Under these two exceptions, the psychiatric record may be introduced into evidence. Otherwise, the psychiatrist-patient or psychologist-patient could preclude the record and its contents. This privilege belongs to the patient, not the doctor.[20] If the patient desires the communications to be introduced, they will be regardless of the psychiatrist's view on the advisability of disclosure. It should be noted the patient's consent must be in writing to be effective.

Information may be disclosed "in house" without a patient release. All information should be released on a "need to know" basis. That is the most effective way to control the flow of information. People who have no "need to know" the information should not have the information disclosed to them. But the information can be disclosed for the purposes of treatment, completing records, a financial audit, or a management audit. Any information that is released for general circulation from these general studies should not contain any patient identifiable data. That will prevent unauthorized and unintentional redisclosure of potentially confidential information.

Drug and Alcohol Abuse

In recognition of the sensitive nature of these problems, the law has provided a special status for this information.[21] These regulations apply to any institution which is even indirectly assisted by the federal government in performing a drug abuse or alcohol abuse prevention program. Drug abuse or alcohol abuse prevention program means any program or activity relating to drug abuse or alcohol abuse education, training, treatment, rehabilitation or research.[34] Whenever a statute is that broad in its jurisdiction, the hospital will probably have to follow it. If any Hill-Burton funds were used to build the building in which the program is housed, the statute is mandatory. If any Medicare or Medicaid patient is admitted to any drug or alcohol program, that also appears to be sufficient to make the statute mandatory.

Specific elements are required for this release form.[22] Most importantly, it must be in writing. A simple oral request or telephone call is insufficient. When the information requested in the release is disclosed, it must be accompanied by a notice forbidding re-disclosure.[23] The notice must either accompany or follow an oral disclosure. Without such proper written authorization, even the patient's status as a patient in the rehabilitation program cannot be disclosed.

The record can be disclosed in certain circumstances even without proper written authorization.[24] It can be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency, to qualified personnel conducting scientific research, management audits, financial audits, or program evaluation,[25] or on a proper court order. However, not just any court order will do. It should be granted only after showing good cause. Good cause shall be determined by weighing the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.[26] A simple subpoena is insufficient, as it is a mere request; a court order is necessary.[27] A court order alone will not require production, although it will allow it. To compel the production of the documents, both a court order and a subpoena are necessary. This special protection is available only to the original records, not to any reports (such as financial audits, management audits, program evaluations, or scientific research, which cannot legally identify a specific patient) produced from the original patient record, which is primarily used as a document to aid in the treatment of the patient.

When a patient on medication is traveling, incarcerated, hospitalized, or otherwise cannot deliver a written release to the hospital at the time the disclosure is needed, a special alternative procedure can be used to release some information.[28] Basically, medical personnel need only orally represent that the patient is currently under their care, has requested his medication, and has consented to such disclosure. Then the patient's status may be confirmed and any information necessary to continue or modify the patient's medication can be released. Upon release, a written memorandum[29] must be put into the patient's chart.

Psychiatric Communications

Psychiatric communications are specially protected at law, as previously discussed.[30] Generally, they cannot be disclosed without the patient's consent. Once they are properly authorized for disclosure by a written release, they must be labelled as confidential.[31] The precise label is required; a substantially similar label is not sufficient.

Disclosure to Parents

A minor may consent to treatment for drug abuse or venereal disease.[32] Any such treatment cannot be disclosed to his parent or guardian without the minor's express consent. Obviously, the parent cannot even be informed of the grounds for refusing to disclose that part of the record. It is suggested the relevant part of the record not be refused, it should simply be not supplied without any unasked for explanation.

Who Can Consent to Release of Information

Any patient with capacity may consent to the release of medical records. This means anyone who has obtained the age of majority can issue a release (18 in Connecticut). Only the minor involved can release his records in drug abuse or venereal disease cases, even to his parents or guardians. Normally, a parent or guardian can release a minor's records until that minor obtains his majority. It is apparently immaterial that the parent may also be a minor.[33] If one parent has been awarded custody of the minor, then it is preferable although not mandatory to get that parent to release the medical information.

The mature minor doctrine may be useful in allowing minors to release their records in certain circumstances. Usually, medical records personnel lack the necessary knowledge to make this determination. But in a rare case where the minor knows the nature, quality, and consequences of his act, his medical record can be released on his authorization. As a practical matter, this will not happen . . . the parent's authorization should also be secured. Since P.A. 79-397 has been signed by the governor on June 14, 1979, minors may be emancipated by court order. Once emancipated, a minor may unilaterally release his medical record as he sees fit.

If a former patient is dead, the executor, administrator, or personal representative may release the medical record. If an adult patient is temporarily unable to consent, then a court appointed guardian will have to release the record. Of course, a record may be released to the extent necessary in an emergency. No consent is necessary, as the emergency creates the power to act.

REFERENCES

1 .5 U.S.C. § 551 (1)

2. 5 U.S.C. § 552 (e)
may also be an exception to the act, even if it did apply . . .
see 5 U.S.C. § 552 (b) (6)

3. 5 U.S.C. § 552a (a) (1)

4. *CIBA-Geigy Corp v. Mathews* 428 F. Supp. 523 (S.D.N.Y. 1977)

5. *Window Systems Inc. v. Manchester Memorial Hospital*
424 F. Supp. 331 (D.C. Conn. 1976)

6. *supra* at 336

7. S. 96-865
H.R. 96-2979

8. Raising an interesting possibility of conflict between the commerce clause and the police power in health services. If either bill is upheld, the police power over health, public safety, and morals will be greatly eroded.

9. *Application of Weiss to Take the Testimony of Mount Sinai Hospital* 208 Misc. 1010, 147 N.Y.S.2d 455, 456 (1955)
Emmett v. Eastern Dispensary and Casualty Hospital 396 F. 2d 931.(D.C. Cir. 1967)
Cannell v. The Medical and Surgical Clinic 21 Ill. App. 3d 383, 315 N.E. 2d 278 (Ill. 1974)
Pyramid Life Insurance Co. v. Masonic Hospital Association of Payne County, Oklahoma 191 F. Supp. 51 (W.D. Okl. 1961)
Rabens v. Jackson Park Hospital Foundation 40 Ill. App. 3d 133, 351 N.E. 2d 276 (Ill. 1976)

10. Conn. Gen. Stat. §§ 4-104, 4-105, and 17-206i(b), as amended by P.A. 79-389 signed into law June 5. All 33 hospitals in the state received $1.00 a year from the state to qualify them for regulation under Conn. Gen. Stat. § 4-104. Effective 10/1/79

11. Psychiatric medical records are specifically exempted from this part of the section.

12. Or his attorney.

13. Reasons for denying access: Conn. Gen. Stat. § 17-206i(b)
1. Would be medically harmful to the patient.
2. Would constitute an invasion of privacy of another person.
3. Would violate an assurance of confidentiality furnished to another person.
Note the reasons for refusing access belong to the facility, not to the doctor, psychiatrist, or psychologist involved. Effective 10/1/79

14. P.A. 79-389 § 2

15. The only possible case where different results might be reached under the two statutes is when a patient has not been treated but has been discharged. Inspection could be denied under Conn. Gen. Stat. § 4-104, leaving Conn. Gen. Stat. § 17-206i (b). Of course, this applies only to psychiatric records.
Another possible difference could occur if Saint Francis Hospital and Medical Center refused to accept the one dollar a year in state aid. Then Conn. Gen. Stat. § 4-104 would be inapplicable although Conn. Gen. Stat. § 17-206i(b) would still be applicable.
Finally, Conn. Gen. Stat. § 17-206i could apply only to psychiatric portions of the record. Perhaps this is what the legislature intended, but this is not clear.

16. *Rabens, supra* at 279

17. In relation to personnel time, office space, and xerox machine usage at cost to the hospital.

18. Conn. Gen. Stat. § 52-146f

19. 1. The person was in fact a patient.
2. Diagnosis
3. Dates and duration of treatment.
4. General description of the treatment which shall include evidence a plan of treatment exists and has been carried out and evidence to substantiate the necessity for admission and length of stay in the facility.

20. Conn. Gen. Stat. § 52-146e

21. 21 U.S.C. § 1175
42 U.S.C. § 4582
42 C.F.R. part 2

22. 42 C.F.R. § 2.31(a)
1. Name of program to make disclosure.
2. To whom the disclosure should be made.
3. Patient's name.
4. Purpose of disclosure.
5. Nature of information to be disclosed.
6. A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon and a specification of the date, event, or condition upon which it will expire without express revocation.
7. Date the release is signed.
8. Signature authorizing disclosure.

23. 42 C.F.R. § 2.32(a)
It must substantially read: "This information has been disclosed to you from records whose confidentiality is protected by federal law. Federal regulations (42 C.F.R. part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose."

24. 21 U.S.C. § 1175(b) (2)
42 U.S.C. § 4582(b) (2)
42 C.F.R. part 2, subpart D

25. Except no individual patient may be identified in any report. *see* 42 C.F.R. § 2.52

26. 21 U.S.C. § 1175(b) (2) (c)
42 U.S.C. § 4582(b) (2) (c)
42 C.F.R. part 2, subpart E

27. 42 C.F.R. § 2.61

28. 42 C.F.R. § 2.33(b)

29. 42 C.F.R § 2.51(e) Consisting of:
1. patient name or number
2. date and time of disclosure
3. nature of emergency
4. information disclosed
5. name of person disclosing information
6. name of person receiving information

30. Conn. Gen. Stat. § 52-146c et seq.
see supra Information that can be disclosed without consent.

31. Conn. Gen. Stat. § 52-146i
"The confidentiality of this record is required under Chapter 899 of the Connecticut general statutes. This material shall not be transmitted to anyone without written consent or other authorization as provided in the aforementioned statutes."

32. Conn. Gen. Stat. §§ 19-89a, 19-496c

33. Conn. Gen. Stat. § 19-142a

34. 42 C.F.R. § 2.11(k)

New Health Practitioners: Progress Report

The following is a report of the AMA Council on Medical Service to the House of Delegates at its Interim Meeting in December, 1978.

At the 1977 Annual Convention, the House of Delegates filed Report L of the Council on Medical Service, "Status Report on Functions and Reimbursement of New Health Practitioners." Report L traced the development and current status of physician's assistants (PAs) and nurse practitioners (NPs), summarized pertinent AMA policy in this area, and reported on the activities of the Council and its Ad Hoc Committee on Functions and Reimbursement of New Health Practitioners.

The purpose of the present report is to inform the House of Delegates of significant developments and activities in this area since that time, and to respond further to specific issues referred to the Council and its Committee for consideration.

Rural Health Clinics Act

CMS Report L (A-77) discussed the Council's—and the Association's—concern with the continuation of Medicare reimbursement policies which disallow payment to physicians for services provided by their employed physician's assistants or nurse practitioners. Under Medicare policies in effect at that time, any reimbursement for physician's assistant or nurse practitioner services was afforded only under the general heading of "medical and other health services," defined in the law as "services . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physician's offices and are commonly either rendered without charge or included in the physician's bills." Excluded under these policies was reimbursement for:

a. any services performed by PAs or NPs where these services are of kinds which are typically and characteristically rendered by physicians (such as prescribing medicine, applying casts or setting fractures, suturing minor lacerations, assisting at surgery, and other activities that involve an independent evaluation or treatment of the patient's condition).

b. all services provided by these personnel in a setting remote from the responsible supervising physician.

c. any in-office services provided by such personnel during a visit when the patient does not see the physician.

Report L (A-77) noted that this lack of reimbursement for PA and NP services decreased the productivity of the medical practice and the availability of medical service, and hindered attempts to use the capabilities of those personnel to the fullest potential. The report encouraged continuation of AMA efforts to amend the Medicare law so as to provide for reimbursement by Medicare to the responsible employing physician for all services provided by these personnel in the physician's office and other settings, whether or not the physician himself also provided service at that time, so long as the ultimate responsibility for these services rested with the physician, and so long as the services were provided in conformance with state laws.

In December 1977, federal reimbursement policies in this area were modified substantially by enactment of P.L. 95-210, the "Rural Health Clinic Services Act of 1977." This new law was based on the premise that, because many isolated rural areas were unable to attract physicians, residents of these areas must rely on clinics that cannot follow the traditional model of physician delivery of services—clinics staffed in many instances by physician's assistants and/or nurse practitioners. The law extended coverage under Medicare and Medicaid to medical services furnished through such a clinic if the services were of a type typically performed by a physician in an office or as a physician home visit. Medicare and Medicaid now reimburse for services performed by physician's assistants and nurse practitioners in "qualified rural health clinics," and such reimbursement is made *directly to the clinic*, rather than the supervising physician or the physician extender*.

In order to qualify for reimbursement under this act—to be "certified for participation"—a clinic must be located in an area designated by the Census Bureau as "rural" and by the Secretary of HEW as a "Shortage area"—i.e., having a deficiency of personal health services or primary medical care manpower. The clinic must have a health care staff which includes one or more physicians and one or more physician's assistants or nurse practitioners. The physician(s) must provide medical supervision and guidance for the physician extenders and other health care staff, prepare medical orders, and review periodically the services furnished and records maintained by the clinic. *A physician must be at the clinic for sufficient periods of time to fulfill these responsibilities—at least once in every two-week period, except for extraordinary circumstances—and must be available at all other times by direct means of communication, for advice and assistance.* Thus, his supervision may be "off-site" rather than "over the shoulder" for a significant percent of the time. The physician member of the staff may be the owner of the clinic, an employee of the clinic or be in independent practice and have an agreement with the clinic. The clinic's physician's assistant(s) or nurse practitioner(s), in addition to furnishing clinic services, are to participate in developing and administering the clinic's patient care policies, assure proper maintenance of patient records, and arrange for patients to receive needed services not available from the clinic itself. The PA or nurse practitioner, too, may be the owner of the clinic, or may be an employee of the clinic or of the supervising physician.

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*A term commonly used in legislation or regulations to denote both physician's assistants and nurse practitioners.

It is important to recognize that the new law and its implementing regulations *do not usurp the state's prerogative to determine the range and scope of services performed by physician's assistants and nurse practitioners, or to set more stringent requirements as to the degree of physician supervision required for such services; rather, they merely provide minimum standards that must be met for purposes of the clinic's qualification for reimbursement under Medicare and Medicaid.* Likewise, while the law and regulations permit a nurse practitioner and physician's assistant to be employed by a rural health clinic, such practitioners may be prohibited by *state* law from being employed by anyone other than a physician or a group of physicians. The regulations would not supplant state law on this point either.

The Act requires only that a rural health clinic staff include a nurse practitioner or physician's assistant under the medical supervision of a physician. The employment and supervisory relationship between the parties is determined by the state law, and will affect the way that the clinic will operate. For example, in those states which prohibit a PA from establishing or working in an independent office, the physician would have to take a far more active role in the daily operation of the clinic. Likewise, in those states prohibiting direct employment of PAs by health facilities, such personnel on the staff would have to be employed by the supervising physician, rather than being an employee of the rural health clinic.

The new law does have a direct impact on a state's Medicaid plan, however, in that any state which legally recognizes the utilization of physician's assistants or nurse practitioners *must* amend its Medicaid plan to provide coverage for the categorically needy for rural health clinic services as these services are defined in the new law. States may exercise their discretion whether to cover rural health clinic services to the *medically* needy.* If, however, outpatient services for the medically needy are already included in the state Medicaid plan, rural health clinic services must be extended to this group as well.

The new law and regulations also define the education and certification requirements that physician's assistants and nurse practitioners must meet in order for their services to be reimbursible in rural health clinics. The regulations require that in addition to being certified by state law, a PS or a nurse practitioner must either: (1) be certified by their respective national certification agency; (2) be a graduate of a nationally accredited program or one that meets certain minimum requirements; or (3) have completed a program not meeting the requirements of (2), above, but having practiced for 12 months in their respectives roles in the immediately preceding 18-month period. This may create an incentive for enacting similar education and certification requirements in those states which do not now have them.

To qualify for reimbursement, the rural health clinic must provide such diagnostic and therapeutic services normally provided in a physician's office, as medical histories and physical examinations, assessment of health status, and treatment for a variety of medical conditions. The clinic must also provide specified laboratory services, be able to treat medical emergencies, have available specified general categories of drugs, and have agreements with other providers for supplying services not available at the clinic, including other diagnostic examinations, physician services, and inpatient hospital care.

Although clinic services can be furnished in the patient's home, in a nearby hospital or nursing home, or any other location needed by the patient, the clinic must also have its own facility at which the patient can receive services, and that facility must receive its own certification as a supplier of services under Medicare and Medicaid.

P.L. 95-210 and implementing regulations provide that Medicare reimbursement for covered rural and clinic services will be based on 80 percent of the reasonable costs of furnishing such services. Payments for services provided by physician extenders and other ancillary clinic staff, and by physicians *at the clinic,* are made directly to the clinic. The physician and the clinic are free to choose the manner in which covered physician's services *outside the clinic* are paid for by Medicare and Medicaid. The physician may agree to be compensated for his out-of-clinic services by the clinic and have Medicare and Medicaid payment for these services made directly to the facility, or, alternatively, payments for covered physician services may be made to the patient (or the physician if assignment is accepted) on a "fee-for-service" basis.

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*The categorically needy under Medicaid are the aged, blind, disabled, or families with dependent children. The medically needy are those who could be self-sustaining except for medical expenses.

Rural health clinics which are an integral part of a hospital, skilled nursing facility, or other institution already participating under Medicare will be paid according to already established methods and principles of hospital reimbursement. "Independent clinics"—those that are not part of a participating institution—will be initially paid by Medicare and Medicaid on a cost-based "all inclusive rate" per clinic visit. This rate is to be calculated at the beginning of the reporting year by dividing total allowable projected clinic costs by the anticipated number of clinic and home visits. It is the announced intention of the Department of HEW to shift "independent clinics" to a fully prospective method of reimbursement by March, 1980, and proposed regulations to begin this shift were expected to be issued before the end of 1978.

AMA testimony on this legislation and comment on its implementing regulations has stressed the desirability of appropriate physician supervision for all medical services provided in such rural health clinics, and the need to implement this law only in conformity with existing state legislation regulating the use of physician extenders. AMA comment has also expressed concern with the complexity of proposed reimbursement methods and resulting inequitable costs to some patients, with potential conflict of interest created by physician extender ownership of a rural health clinic, with inappropriate specificity in requirements for laboratory services and drug formularies, and with other specific aspects of the law and its regulations.

There has been a relatively low rate of applications to date from facilities wishing to be certified as rural health clinics. As of September 20 of this year, 900 applications for certification had been returned from a total of nearly 2,600 distributed to facilities potentially qualified. Of these 900, 346 were disqualified for ineligible location or staffing, 24 were denied certification, 20 withdrew during the certification process, 130 had their certification pending, and 215 were approved for participation. The Department of HEW had originally anticipated having 900 such clinics approved for participation by this date.

The Council and its Committee on New Health Practitioners will continue to monitor the development of this program, in an attempt to insure its implementation in a manner most conducive to quality medical care.

Model Amendments to State PA Legislation

As indicated in CMS Report L (A-77), the majority of states (43 currently) have enacted statutes authorizing the use of physician's assistants. While some of these statutes are closely in accord with Association policy on this subject, other statutes or pending legislation contain such troublesome features as overly rigid and explicit role definitions, arbitrary prohibitions against the PA's performance of specific functions, insufficient physician participation in delineation of PA roles and functions, or duplication on the state level of accreditation and certification programs already operational nationally.

For that reason, the Council on Medical Service recommended to the Board of Trustees in December, 1977, that model legislation be developed authorizing the use of physician's assistants, for the guidance of states in drafting or amending undesirable features in existing statutes in this subject area. Because the great majority of states already had legislation pertaining to physician's assistants, it was the opinion of the Council on Legislation that the most practical approach to improving and eliminating undesirable features in such legislation would be through the development of a group of suggested amendments, for application as seen appropriate, rather than a single model bill. Such amendments could be used individually, or—in the case of states currently without PA legislation—used in toto as the format for a bill if desired. With the concurrence of the Board of Trustees, such amendments were developed jointly by the Council on Legislation and the Council on Medical Service, and will be submitted to the Board of Trustees for approval.

To provide further assistance to states grappling with the development of implementing regulations for PA legislation, the Council on Medical Service and its Ad Hoc Committee on New Health Practitioners are presently reviewing regulations already developed by a number of states, to identify those which might best serve as models in this area.

Recommendation 40 of Commission on Cost of Medical Care

Recommendation 40 of the Commission on Cost of Medical Care called for modification of state legislative restrictions on the use of allied health personnel under the supervision and direction of physicians. In its report to the House of Delegates at the 1978 Annual Convention, the Board of Trustees noted current Association policy in this area as: (1) Encouraging the delegation of tasks to qualified allied health personnel within the limits of good quality medical care; (2) calling for removal of barriers to delegation in state medical practice acts; (3) endorsing performance by allied health personnel of their duties within the legal limitations of applicable state laws; and (4) endorsing freedom of physicians to delegate tasks to allied health personnel within the scope of their expertise and such laws.

The Board saw Commission Recommendation 40 as generally consistent with past AMA policy in this area, and accordingly recommended its endorsement. Concerns were expressed by the House, however, as to the accuracy of current AMA policy as cited by the Board in relation to removal of barriers to delegation in state practice acts, and Commission Recommendation 40 was accordingly referred through the Board of Trustees to the Council and its Ad Hoc Committee for study and clarification.

The Council and its Committee have reviewed past Association policy in this area, and report that the Board's citation was indeed accurate. At the 1970 Clinical Convention the House adopted Board of Trustees Report E, "Licensure of Health Occupations." This report recommended:

> "That state legislatures be urged to amend state medical practice acts to remove any barriers to increased delegation of tasks to allied personnel by physicians."

Report E (C-70) pointed out that the majority of existing state medical practice acts do not define the practice of medicine in terms of specific functions, but that the amendment of medical practice acts as suggested above would codify the physician's recognized right to delegate patient care functions to competent personnel consistent with the patient's welfare, and might serve to reassure and encourage physicians to innovate in the use of manpower.

More recently, the House adopted Report K of the Council on Medical Service, "Inappropriate Restrictions on the Use of Assistants to the Physicians." Report K (I-77) expressed concern at any provisions in state legislation, whether in the medical practice act or elsewhere, which would arbitrarily restrict the physician's ability to delegate to competent allied health personnel. Such provisions were seen as directly contrary to the interests of good patient care, regardless of the field of medical practice or type of assistant to which such restrictions were applied, and the report recommended, in part, that "The physician should be allowed by law to delegate specific procedures to allied health personnel working under his supervision and direction which are commensurate with the competence of such personnel and the needs of the patient."

The intent and the effect of both this recommendation and that in Board of Trustees Report E (C-70) would *not* be to foster the independent performance of medical functions by allied health personnel, but rather to reaffirm the physician's right to delegate such functions to allied personnel *who work under his supervision, direction, and responsibility.*

The Council and its Ad Hoc Committee believe that such reaffirmation is highly appropriate and particularly needed if the physician is to be able to use such newer categories of health personnel *as physician's assistants* flexibly and effectively in patient care. Indeed, the model amendments to state legislation referred to earlier in this report are directed to such a goal.

Based on the foregoing considerations, the Council recommends that the Board of Trustees response to Commission Recommendation 40, calling for endorsement of that Recommendation, be adopted.

State Regulation of Expanded Nursing Functions

CMS Report L (A-77) reported that as of May 1977, 29 states had enacted amendments to their nurse practice acts which expanded the scope of permissible nursing duties to include certain medical functions, provided that additional education and clinical requirements were met. Statutes in 19 of these states provided that nurses could engage in the practice of such medical activities as are approved by the state medical board and the state board of nursing, and thereby delegated to those boards the authority to jointly determine which medical activities may properly be performed by nurses. Currently, 38 states have amended their practice acts to allow expanded nursing functions, and 27 of these provide for joint determination by the state medical and nursing boards to establish expanded medical functions which professional nurses may appropriately perform.

The Council and its Committee believe that this "joint determination" approach is extremely important, and that it should be provided for by statute in all states. The National Joint Practice Commission, co-sponsored by the AMA and the American Nurses' Association since 1971, has also recommended that the performance of tasks by nurses that are not commonly accepted nursing tasks should be mutually agreed upon by the nurse and the physician. The NJPC has encouraged and assisted in the formation of counterpart state joint practice committees, to undertake just such joint examination of expanded professional roles; there are currently such joint practice committees in 36 states.

The NJPC itself is also examining state legislation in this area, to identify further changes needed to permit optimum use of nurses in expanded medical service roles consistent with safe and effective patient care. A special seminar on legal aspects of the practices of health care professionals was held under NJPC sponsorship in September of this year, and the Commission's Third National Conference on Joint Practice, held in November, also gave special attention to this subject.

The foregoing summarizes some of the significant activities and developments dealt with to date related to the functions and reimbursement of new health practitioners. The Council and its Committee will continue to study issues and problems arising in this field, and will submit further reports to the House of Delegates as is deemed appropriate.

To Cure Sometimes, To Relieve Often, To Comfort Always

MORRIS A. WESSEL, M.D.

Hippocratic Oath

"I swear by that which I deem holy, that, according to my ability and judgement, I will keep this oath and this stipulation—to reckon him who taught me this art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same light as my own brothers, and to teach them this art, if they should wish to learn it without fee or stipulations; and that by precept, discourse and every other mode of instruction, I will impart a knowledge of the art to my own sons, and those of my teachers, and to the disciples bound by a stipulation and oath according to the law of medicine, but to none others.

I will follow that system of regimen which, according to my ability and judgement, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.

I will give no deadly medicine to any one if asked, nor suggest any such counsel. With purity and with holiness I will pass my life and practice my art. I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work.

Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and never misuse my trust for the seduction of patients. Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men and women, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this oath unviolated, may it be granted to me to enjoy life and practice of the art, respected by all men, in all times!

But should I trespass and violate this oath, may the reverse be my lot!"

(This version of the Hippocratic Oath was revised from the traditional statement by members of the Yale University School of Medicine, Class of 1979).

There is a sentence in the Hippocratic Oath which I wish to consider as it applies to the times in which we live and practice our art. It is the line which reads, "*I will follow that system of regimen which, according to my ability and judgement, I consider for the benefit of my patients!*"

This advice poses an immense challenge for a physician today as he or she cares for patients. It is difficult to remember to use all that one has learned and to apply all one's ability and judgement in every contact with patients. There are, nevertheless, some items which deserve high priority in our daily activities as physicians. Whenever we take a medical history or examine a patient or perform surgery or consult briefly, we are at that moment the patient's personal physician. We need to assume our professional role so that the doctor-patient interplay offers maximun relief to a fellow human being who is suffering. This should always be a physician's goal whatever the cause of the patient's complaints and symptoms.

Several ideas emerge as one considers how a physician may be as successful as possible in alleviating a patient's distress.

The first point is to remember that in spite of the vast technological advancements in medicine in recent

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This version of the Oath of Hippocrates was administered by Dr. Thomas Forbes, Professor of Anatomy, Yale University School of Medicine and the remarks by Dr. Wessel were presented at a special ceremony held on May 21, 1979.

decades, one of the most powerful therapeutic tools available to any physician remains the art of listening. Careful attention to what a patient says often leads to an unsuspected diagnosis. Even more important, careful listening convinces the patient that the doctor cares about him and the fears, anxieties, worries and symptoms which lead him to seek our help. No other professional person can listen with so much authority. As the doctor listens, the patient feels that all available accumulated knowledge, wisdom and power, and even some degree of magic is being concentrated on his care. He develops confidence and trust that the physician will do everything in his power to treat his sickness and make him as comfortable as possible.

Laboratory studies, X-rays and other diagnostic procedures may aid in determining the diagnosis; yet the patient often continues to be worried, frightened and miserable. The physician must explain carefully the cause of the illness, the treatment plan and provide ample opportunity for discussion of the patient's specific questions, fears and anxieties.

A second point often forgotten is the need for a physician to direct, coordinate and guide the patient's course through the complicated pathways of consultation, examination and evaluation. This is a difficult time-consuming task, but unless one doctor assumes this responsibility, the patient may feel as if he or she has been on a conveyor belt, stopping here and there for testing, examination, evaluation and consultation. Once having gotten through the maze he is somewhat exhausted; he may also be a bit anemic. The patient often feels no better than when he initially sought help. He may have little understanding of his illness, or how to improve his well-being and what to expect in the future. One doctor—often the primary or personal physician—must *put the act together*.

When a disease of a malignant nature or critical nature exists, the personal physician needs to understand the patient's feelings, stand by, listening, supporting and comforting this fellow human being who at first may deny the possibility of this serious diagnosis. This initial denial makes the intolerable, tolerable! The patient later may become bitter and angry. He is likely to be seized with intense feelings of powerlessness as he begins to deal with the reality of his diagnosis. The personal physician who assumes responsibility at this critical moment can provide invaluable stabilizing support thruout the remainder of the patient's life, even though many specialized consultants may administer the definitive treatment.

When a patient dies, physicians experience a sense of loss. At times we feel defeated. We feel as though our scientific knowledge and skill, and that of our colleagues has failed. However a physician who continues his long-standing relationship with a family and assumes an important supporting role can be very helpful. Bereaved individuals often turn to their doctor with complaints of restlessness, exhaustion, bodily aches, insomnia, weight loss, loneliness, bitterness and other symptoms associated with mourning.

How much a physician extends himself during bereavement depends on the confidence one has in one's own ability to bear this distress, one's understanding of the grief process and how worthwhile one thinks it is to be available to suffering family members. As distressed as they may be, bereaved individuals appreciate greatly and feel comforted when their physician demonstrates that he cares by arranging for an office visit or by stopping by the home. The bitterness and anger expressed by relatives after the death of a loved one may appear to be focussed on the doctor, but this is only a normal human reaction following an intense loss. The physician is the recipient of these feelings. He provides an important therapeutic force when he accepts these feelings which stem from the patient's painful process of grieving and mourning.

The physician who feels a sense of failure following the death of a patient can experience personal and professional satisfaction in his ongoing relationship with the bereaved family members as he helps them through the difficult period of grief and mourning and finally helps them to regain equilibrium.

I would like to conclude with the suggestion that the French proverb enunciated so frequently by Edward Trudeau, "*To cure sometime, to relieve often, to comfort always*" be an additional guideline in whatever sphere you work as physicians. The opportunities and challenges you face have never been greater. I wish you good luck. I know you will have a great deal of professional and personal happiness in the years ahead.

The President's Page

The recent passage of a resolution at the AMA House of Delegates urging state medical societies to develop programs of public information and public relations was long overdue. We at CSMS were only one step ahead of the AMA and despite strong support for the principles of public information and public service, to date our efforts have amounted to no more than lip service. Thirty-second radio and television spots in support of "No smoking," active exercise and a balanced diet in combination with periodic visits to the family doctors may have sufficed in a bygone era to pass for attempts at public information, but today that's totally inadequate in the face of mounting attacks upon our motives and integrity by both consumer groups and govermental agencies.

The time has come for us to speak out much more forcefully on issues that deeply affect the lives of our patients and the climate under which we physicians wish to practice. Input to the media comes from many sources, and those receiving the information do not have the expertise to recognize half-truths from the real truth.

When the department of HEW writes letters to Medicare beneficiaries extolling the virtues of their neighborhood HMOs and less than subtly attempts to wean our patients from us, who is it that cries, "Hold on there—enough of that?" When this same department pushes for support of 50,000 member or more HMOs, who will inform the public that the reason for this is because HMOs of lesser membership are a dismal financial failure which we taxpayers are supporting?

When the federal government advocates second opinion programs prior to surgery for procedures like tonsillectomies because of the high risk of mortality whose responsibility is it to document that hospital records from all over Connecticut in the past two years do not show a single death associated with a tonsillectomy?

When the profession is indicted in newspaper articles which intimate that physicians avoid the care of the poor in this state because of low welfare payments, who will counter by pointing out that the overhead cost of caring for the patient is often greater than the fee given to the physician by the state and that the state is often months in arrears in payment of those fees? And finally how many people in this state know that there are physicians in Connecticut today who care for patients without charge and prefer to continue to do so rather than tolerate further government intervention.

To date, no informed media person has come forward with an offer to do this job for us. It becomes therefore, our sole responsibility and we must take it on. But, as always, there is a price to be paid! The cost to us will be in 1. time, 2. cash and 3. commitment.

This program can not be initiated by novices and we are novices. We need professional help in the field of public information because facts have to be gathered, information has to be collated, and it has to be disseminated properly. This program may require the purchase of broadcasting time and advertising space but it is a task that urgently needs doing. We are doomed to failure, however, if we do not recognize that the first step in the evolution of this program is the education of our own physicians in this state and the enlistment of their support.

We physicians in Connecticut see approximately 100,000 patients each working day. If we are to survive this adverse media onslaught against us we must take the time not only to discuss health matters concerning each individual patient but also counter the untruths that are being disseminated if we deem them untrue. Furthermore we have an obligation to make our views known about health care delivery sytems being proposed by different politicians.

Our good intentions will be to no avail, however, if we fall prey to attempts by some within and without our ranks to fragment us by setting primary care physicians against surgeons and super-specialists against both. The key to our success in this endeavor is sticking together! If there are grievances within our ranks, we must close our ranks and resolve them fairly and without rancor. Remember: "A house divided will not survive." How could we ever permit that?

Edward A. Kamens, M.D.
President

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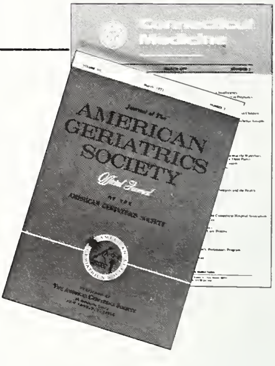

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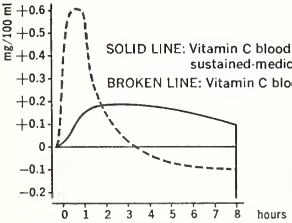

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Reflections from the Dean's Office

Fides Medici

ROBERT U. MASSEY, M.D.

It was pleasant to find that my 1952 unabridged Webster's International Dictionary does not have the word *holism,* nor does the Oxford. It does appear in Webster's New Collegiate, 1971, and is derived from *hol-* plus *-ism.* That qualifies it as a barbarism: the first syllable is the English word *whole,* and the second is a Latin suffix, *-ism.* Dropping the *w* disguises the northern origin of *whole* and gives the word a Greek look. *Wholeness, integrity,* or *oneness* might have done, but perhaps there was need for a new word, and we should impoverish our language if we wiped out all words of hybrid derivation. Fowler's comments are about right:

> "That barbarisms should exist is a pity; to expend much energy on denouncing those that do exist is a waste; to create them is a grave misdemeanor; and the greater the need of the word that is made, the greater its maker's guilt if he miscreates it."[1]

The phrase *holistic medicine* appears more and more often in the press and in lecture circuits to signify some sort of medicine different from the kind currently practiced. Those opposed to technology in hospitals, chemotherapy for cancer, lithium for depression, reductionism in biology, and research in medical schools speak of holistic medicine as an alternative to whatever it is that allopaths do. Not all would admit to motives of anti-science or anti-technology. Certainly we all know that in our zeal to cure we may lose sight of the patient as a person. In attending to the part we may forget the whole; instead of treating patients we may deal with clients in our ponderous bureaucracies, the hospitals and clinics.

But many of the holists seem to have broken with scientific medicine, or at least hide their hostility with difficulty. Another cult may be no more risky than Christian Science, chiropractic, or homeopathy, all of whose origins were intertwined with a thread that runs right on into holistic medicine. Tragedies occur when cultic principles are doggedly applied, but the greater danger is in letting the virus of cultism into scientific medicine.

Except for a score or two of careful observers or devoted practitioners during the past three millenia, medical history until recently has been one of unrelieved failure. Only in the past hundred years has medicine begun to fulfill its promises. Although many of the great victories lie in the future, those that have been won may be ascribed to technological inventions and the growth of biological science.

The practice of medicine is an art; it is not only technology or applied science. It is the artistic use of both in caring for human beings in matters relating to their health. Without the science and the technology, the artistry would be only as effective as unassisted nature in eliminating disease and repairing injury. That capacity is by no means trivial, but to holistic medicine or megavitamins may be ascribed what is justly due to nature.

Because nature has selected well, we may waver in our faith in the power of science, but there can be no going back. Science will go on as long as we are around; there will always be more to know, another question to get an answer to, and, with each new understanding, our capacity to apply our art "for the uses of life," as Bacon hoped, increases.

Withdrawing from the high ground of science would not be accepted for long. Our minds wouldn't allow it, but any retreat could delay some victories in medicine for decades.

When Alfred Russell Wallace, the nineteenth century naturalist, broke with Darwin on the issue of human evolution because, although he believed that natural selection accounted for the origin of all other species, he could not accept it for man, Darwin wrote: "I differ grievously from you, and am very sorry for it."[2] He recognized that once our hands had seized the plow of science, there was no looking back.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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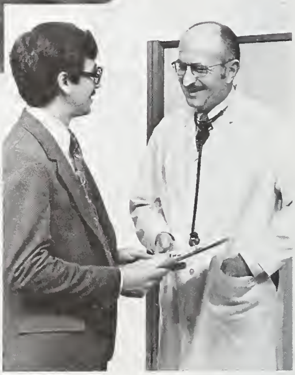

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The Death of Chad Green

JOSEPH M. HEALEY, J.D.

As Karen Ann Quinlan became a symbol of the problems of life support systems and their appropriate use, so now Chad Green has become a symbol of the problems of laetrile and the appropriate range of parental discretion in health care decisions for their children. It is ironic that it was during the same year the United States Supreme Court rejected the request of a group of terminally ill cancer patients to have access to laetrile and during the same year the United States Supreme Court struggled to find a balance between the rights of adults and the rights of minors in the health care process, that the Green drama should reach its tragic conclusion. It is also ironic that the death of Chad Green should occur during the International Year of the Child when world attention was focused on the rights of children.

Chad Green was born on December 18, 1975. On September 1, 1977, he was diagnosed as having acute lymphocytic leukemia. He was hospitalized in Omaha for chemotherapy. By September 30, 1977, the leukemia was determined to be in a state of remission. The Green family, partially because of their aversion to cranial radiation therapy, left Nebraska and moved to Scituate, Massachusetts to permit Chad to receive treatment without cranial radiation at Massachusetts General Hospital. On October 19, 1977, Chad began treatment at the Pediatric Hematology Unit of Massachusetts General Hospital under the care of Dr. John Truman. The acute lymphocytic leukemia was of the null-cell type. The treating physicians believed that if Chad followed the treatment protocol, then there was at least a 50% chance of his survival. His age and the early induction of remission were factors supporting optimism. In November, the parents for the first time refused consent for the continuation of treatment and without disclosing it to the physician, discontinued the chemotherapy provided at home. In January, 1978, an elevated white blood count was detected which the parents failed to explain. In February, 1978, one of the parents indicated that the medication was still being taken. Blood studies at this time revealed 4% leukemic cells. The physician assumed that leukemia had recurred while the patient was on chemotherapy. In such cases the disease is extremely likely to be fatal. In the course of discussing the options available, it became clear that the mother had stopped giving their son the chemotherapy. The parents refused to consent to the reinstitution of therapy despite the persuasive efforts of Dr. Truman. He then sought a court order requiring the Green parents to allow the child to receive treatment again. The request was granted. The treatment was resumed and remission was induced for a second time.

There followed several efforts by the parents to regain control of health decisions affecting their son. During the first series of cases which culminated in a Massachusetts Supreme Court decision in July, 1978,[1] the parents protested the need for chemotherapy. During the second series of cases which culminated in a second Massachusetts Supreme Court decision in August, 1979,[2] the parents conceded the necessity of chemotherapy but sought to supplement it with a program of metabolic therapy involving the daily administration of enzymes, large doses of vitamins and laetrile. The result in both cases was similar: the Court concluded that the best interests of the child required the continuation of the cancer chemotherapy and a limitation on the authority of the parents to interfere with its administration. In the second case, the Court also rejected the proposed metabolic therapy as posing significant risks to Chad's health. The Green family left for Mexico in January 1979. Our knowledge of the precise events preceding the death of Chad is limited. It is alleged that the parents discontinued chemotherapy during the late summer of 1979 and that he died within three months.

A closing section of the second Supreme Court case sums up the feeling of frustration which many observers felt:

> The judgment of the parents has been consistently poor, from the child's standpoint, and his well-being seriously threatened as a result. Their persistence in pursuing for their child a course against all credible medical advice cannot be explained in terms of despair of a cure, or by the suffering of serious side effects of chemotherapy. The chance for cure with chemotherapy is good; the side effects of chemotherapy in this case have been minor and readily controllable. The parents' actions must be viewed with compassion, but beyond doubt their poor judgment has added immeasurably and unnecessarily to their difficulties, and to to those of the child.[3]

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JOSEPH M. HEALEY, J.D., Assistant Professor of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington, CT.

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EDITORIALS

Doublethink Confounding to Your Health

In George Orwell's disturbing novel Nineteen Eighty-Four (can 1984 be so near?), the language of the society Big Brother rules is called NEWSPEAK. In its government-authorized vocabulary, words have been deleted and modified so as to produce the phenomenon of DOUBLETHINK which is "the power of holding two contradictory beliefs in one's mind simultaneously and accepting both."

If the novel is worrisome and produces feelings of concern, how much more disturbing are the 1979 examples of doublethink so common among certain planners and regulators of health care. For (as in the controlled society of Orwell) some proponents of big-brotherism in our state and nation are performing the mental gymnastic of doublethink in health related matters.

Example: All of our citizens should have unrestricted access to health care—but the total cost of health care must not rise in the process. That is, more people should receive care but the total bill should not go up.

Example: The physician must make no errors—but he should reduce his use of diagnostic tests.

Example: Everyone should have easy access to the current state of the art—but we can't afford to put the current state of the art where everyone can have easy access to it.

Example: Humanism should be part of medical care—but expensive humanistic devices (like CAT scanners) may not replace uncomfortable techniques (like angiography or pneumo-encephalograms) because we need Toyotas and not Cadillacs. (Does this mean everyone gets a Toyota or some get Toyotas and some Cadillacs?)

Example: Ineffective hospital boards of directors and their hired administrators should prevent physicians from overordering and resist physician's efforts to add to modern technology—but the boards are to remain responsible for the quality of care provided the patients.

Example: We need more doctors—but health care should cost less.

Example: People shouldn't have to wait very long for nonurgent unscheduled care (as in emergency rooms or private offices)—but the number of personnel in the emergency room or the number of private offices needed to give the care promptly should be constrained to save money. (This is a variety of the "we have too many doctors—we have too few doctors" philosophy of many congressmen.)

Example: The government should control the health care system—but the government can't be allowed to meddle in private insurance, delivering mail or controlling oil companies because the government can't control anything really important.

In "1984" no one ever expected Big Brother or his associates to wait in line for their rationed care or to be filtered through unnecessary and delaying second opinion procedures. No one would have expected a leader to be inconvenienced by childbirth or children's hospital care affecting their family. We see that today when certain hypocritical regulators or legislators insist that the system that they themselves are creating be bypassed for they themselves.

Of course, some of the most zealous regulators of our current health care system don't believe in their personal health care so they are not hypocrites, but they do deal in "doublethink."

Example: "Physicians don't do enough about preventing disease and must be made to do so" (said by a regulator who smokes, drinks and speeds but expects to stay well because he jogs).

Example: "The emphasis in health care must be on preventive medicine" (said by a legislator who believes in orthomolecular medicine and Laetrile).

Example: The health care planner who frequently advises people about their use of the system and demands they insist upon preventive care who has not had a physical examination since the age of 16 because of fear of what would be found.

Finally, we have two examples of fiscal double-think.

Example: The planner who supports community psychiatry and discharges the mentally ill from state hospitals into the streets to save state monies—but deplores their neglect when they get there because the state monies never left the institution the patient left.

Example: The current trend to shift the financial burden for health care for the medically indigent from the state which mandates it to the private system which is not adequately funded by the state to provide it.

Oh well, 1984 is still more than four years away. Or is it?

Howard J. Wetstone, M.D.

Director of Ambulatory Services
of Hartford Hospital

Reprinted from The Hartford Courant

The Shah and Confidentiality

Mystery still surrounds details of the illness of the former Shah of Iran. We do know that no illness in a single individual has ever had the politically catastrophic results on the United States, or probably on the world, as his. President Carter stated that he was solely responsible for admitting him Oct. 24 from Mexico City—for humanitarian reasons based on his illness. The Shah was discharged from the New York Hospital on Dec. 2 as soon as his medical condition permitted—to recuperate in San Antonio. He left the country Dec. 15 as soon as he was assured of asylum by Panama.

One issue of special interest to physicians in the Shah's case is the confidential relationship between patient and physician. This was epitomized in the headlines of an article in the *New York Times* by reporter, Lawrence K. Altman, MD, "The Shah's Right to Privacy versus the Public's Right to Know." Related to confidentiality are the patient's right to privacy and privilege.

His physicians and hospital adhered strictly to the centuries-old Hippocratic Oath on confidentiality. Nor need they ever breach his confidentiality even after his leaving their care, the country, or after his death. Whatever information has been given to the public by his physicians was screened by him. Though their honesty in such reporting has not been questioned, the information has been contradictory, confusing, and incomplete. While physicians commend them in their strict adherence to the Code, it has been frustrating to reporters, who claim they represent not themselves but the public. Later, his medical history may be of political importance only to assess the President's judgment in admitting him to our country instead of his being treated in Mexico—or some other country.

Though the Hippocratic Oath carries no exception to its rule on confidentiality, the Principles of Medical Ethics of the American Medical Association does: ". . . until he [physician] is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or the community." Was it necessary to make public details of the Shah's illness "in order to protect the welfare of the community?" The physicians and hospital judged it was not; and most physicians would agree. States differ in their legal requirements for physicians to report certain diseases: examples are compulsory reporting of some contagious diseases, bullet wounds, and child abuse. It is seldom that a physician's ethical obligation conflicts with his duties as a citizen; if it does, his judgment in what and how much to report is necessary. Some reporters pressured the Shah's physicians to give more, even complete information to the public, but they did not.

Confidentiality and the right of privacy may overlap, but the differences though subtle are important. The legal right of privacy originated in an article by Mr. Justice Louis D. Brandeis and Samuel D. Warren in *The Harvard Law Review* in 1890. Because there was at that time no common-law protection of one's privacy, they asserted that the law should recognize it.*

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* Joseph M. Healey, JD, Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, will discuss the legal issues in the Shah's case in his monthly column in future issues.

Subsequently it was enforced as a distinct legal action, culminating in its recognition by the U.S. Supreme Court in the contraception and abortion cases, involving the privacy of married couples and women. The right, however, is circumscribed. Whereas an individual as a public citizen has this legal right, public figures, public in the eyes of the law, may not. For example, it is probable that reporters claiming First Amendment protection could report any details of the Shah's private life, including his illness, because he is a public figure. Public information about such individuals by a reporter is actionable only if the material is libelous and written with malice. But though physicians may consider confidentiality as an ethical concept, a patient may be successful in a legal action against his physician if he betrays the confidential nature of their relationship.

As for privilege, this is a legal concept, epitomized by the legally protected confidential relationship between lawyer and client, between husband and wife. Unless specifically superseded by statute or the courts, the common law does not recognize confidentiality between patient and physician. In some states, it is legally protected, especially between patient and psychiatrist.

It is probable that there will be congressional investigations after the hostages have been returned to determine whether or not the President used good judgment in admitting the Shah, considering the risks to the patient. But this is a political decision. Some people, even physicians, doubt that his illness was the real reason for admitting him. Congressional committees have the right of subpoena. Will it be legally possible for them to require physicians to testify, and to examine the Shah's hospital and medical records? Many unanswered questions have already been brought up by the press and public, such as: Could the Shah not have been treated in Mexico? Did Mexico not have the medical facilities and expertise? Should not cancer consultants or a surgical team have gone to Mexico to diagnose and treat the Shah?

In medical malpractice court proceedings, the plaintiff-patient waives his right of confidentiality of his records. Physicans can be subpoenaed to testify as witnesses, and also act as expert witnesses. It is possible that they may act in similar roles in congressional hearings. And many members of Congress are lawyers.

The Shah's physicians and the New York Hospital have demonstrated in an exemplary fashion to the American public how the medical profession is protecting them in their confidentiality. Practically all physicians agree with and commend their conduct.

Fred Fabro, M.D.

Letters to the Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed by all authors, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.

DR. ARTHUR HEUBLEIN AND RADIOLOGY AT HARTFORD HOSPITAL

To the Editor: I was much interested in the articles about the Hartford Hospital in the November issue of Connecticut Medicine since I am a graduate both of the Internship Program and the Residency Program in Radiology. I would like to point out, however, one major error in the article about Medical Education at Hartford Hospital. This article states that the Radiology Department was developed by Dr. Gilbert Heublein about 1932. Actually, the department was founded by Arthur Heublein, a pioneer Radiologist before World War I, and was a very well established department in the 1930's under the guidance of Drs. Douglas J. Roberts and Ralph T. Ogden.

John Burbank, M.D.

Meriden, CT

The above letter was referred to Marjorie Bingham who offers the following reply:

To the Editor: Dr. Burbank is entirely correct in stating that Dr. Arthur Heublein rather than Dr. Gilbert Heublein, his son, developed the Radiology Department. The Hartford Hospital Annual Report for the year ending September 30, 1907 indicated that an X-Ray Department opened April 1, 1907. In the Superintendent's Report for the year ending September 30, 1926 the opening of the Capewell Memorial X-Ray Building June 1926 was reported. This building provided space for X-Ray and deep X-Ray therapy.

In the Hartford Hospital Annual Report for the year ending September 30, 1932 announcement was made regarding the death of Dr. Arthur Heublein. It was noted that he was appointed electrotherapist in 1906 and in 1910 roentgenologist and radiologist. The announcement stated that he was responsible for the development of the X-Ray Department. Unfortunately, the notes recorded from this announcement were translated inappropriately and resulted in the incorrect statement about the development of the Radiology Department in the article about Medical Education at Hartford Hospital.

Marjorie Bingham

Coordinator of Medical Education Programs
Hartford Hospital, Hartford, CT

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Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

COUNCIL MEETING

Thursday, December 13, 1979

Attendance

Present were: Drs. James, Canzonetti, Backhus, Mendillo, Sadowski, Freedman, Van Syckle, Fabro, Whalen, Jr., McGarry, Magram, Parella, Barrett, Zlotsky, Jameson, Abbot, Seide, Eslami, Tierney and Bobruff.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Sweeney, Mr. Brunell, Mr. Fiorentino and Mr. Tomat (FCMA).

Approval of Minutes

It was VOTED to approve the minutes of the meeting of October 31, 1979, as published and distributed.

Reports from Physicians Serving on State and Federal Agencies

Prior to asking for reports, Dr. Canzonetti read aloud a letter from Governor Grasso to Dr. Mehdi Eslami appointing him to the Statewide Health Coordinating Council. The Council joined Dr. Canzonetti in a round of applause for Dr. Eslami Hartford County PSRO—Dr. Andrew J. Canzonetti reported that the hospital study will be reviewed soon by the Connecticut Commission on Hospitals and Health Care.

PSRO II—Dr. John Mendillo mentioned that the PSRO was undergoing a reorganization and that an executive director had been hired recently.

Statewide Professional Standards Review Council—Dr. Gioacchino Parella reported that the cosponsored program on the shortage of extended care facilities had been successful and that a report from Mary Healy was expected soon.

HSA I—Len Tomat mentioned that a series of public hearings had been held on the health plans and that the final plan would come before the board on December 18.

Resignations

Letter from Dr. Stuart Ragland—The Chairman of the Council read a letter from Dr. Stuart Ragland, Jr., Colebrook, submitting his resignation as Speaker of the House of Delegates and from all other committees on which he had been serving as a member. It was VOTED to accept his resignation with regret and to send him a warm letter of thanks expressing the gratitude of the Society for his many services. The following action was taken on the various posts held by Dr. Ragland:

Speaker of the House of Delegates—According to the CSMS Bylaws, Dr. Joseph S. Sadowski, Vice-Speaker, becomes the Speaker. It was VOTED to table the appointment of a Vice-Speaker until the February meeting of the Council.

Judicial Committee—It was VOTED to appoint Dr. Laura Morgan, Stamford, Chairman of the Judicial Committee.

Committee on Legislation—No replacement necessary at this time.

Society's Representative to the Connecticut High Blood Pressure Program: Dr. Frank Abbot, Hartford, was appointed to replace Dr. Ragland as the CSMS representative.

Advisory Council to Connecticut Poison Center

The President of the Society received a letter from the Dean of the School of Pharmacy requesting the Society to appoint a representative to serve a two-year term beginning 1/1/80 as a member of the Advisory Council. It was VOTED to appoint Dr. James E. O'Brien, Farmington, as the Society's representative.

Connecticut Medical Examining Board

Dr. Lawrence Pickett, Chairman of the Connecticut Medical Examining Board, reviewed for the Council recent activities of the Board. He mentioned that the Sunset review legislation had interrupted progress of the physician rehabilitation program since survival of the Board had become an issue. Dr. Pickett reported that public hearings had been held and that recommendations of the legislative review committee would be made public by January 1. He acknowledged that the CSMS had offered assistance to the Board and had provided testimony on the subject at the hearings. Dr.

Pickett indicated his willingness to keep the Council apprised on Board developments and to work with the CSMS to strengthen the Board. In the spirit of the House of Delegates resolution "to continue to pursue cooperative efforts with the Connecticut Medical Examining Board to assure its proper functioning following the Sunset Law revision process", the Council assured Dr. Pickett of its interest in providing whatever assistance is necessary.

Medicare - Medicaid Program

At its November 15 Meeting, the House of Delegates voted to refer the following Medicare-Medicaid Program coordination resolution to the Council for further deliberation and action:

RESOLVED: That the CSMS convey to our Congressman that we favor legislation that would combine Medicare and Medicaid using one current procedural terminology and reimbursement practice.

Dr. Francis Klimas appeared before the Council to discuss a Medicare-Medicaid program coordination resolution which he had introduced before the House of Delegates and which had been referred to the Council. Mr. Stephen Press, Director of the Medicaid Program, also was present to review the program and answer questions. He mentioned that he expected by 1981 a uniform CPT Medicare and Medicaid procedure and diagnostic code. Following lengthy discussion the following action was taken:

VOTED: That the Council recommend to the House of Delegates that the resolution not be approved (Unanimous)

VOTED:That the Chairman of the Council appoint an Ad hoc committee using members of the Liaison Committee with the Department of Income Maintenance, Committee on Third Party Payments, officer of the Society, etc. to fulfill the goal of making the Medicaid Program reimbursements equal to the Medicare Program.

AMA Convention

Dr. Guy Van Syckle reported on activities at the recently concluded AMA Convention and mentioned that the AMA House of Delegates:

Reaffirmed its policy on NHI

Urged development of strict new regulations curbing smoking on airlines.

Reaffirmed its support for continuation of the PSRO program.

Urged Medicare officials to stop misusing the term "reasonable charge."

Reaffirmed its confidence in and support of the Voluntary Effort.

Filed a report of the AMA Council on Medical Education and directed that its suggestions become an "agenda of issues for discussion".

Called for development of more sites for disposal of low level nuclear wastes.

Drs. J. Alfred Fabro, Sidney Cramer, W. Raymond James and Jerome K. Freedman also reported on their views of the Convention.

Report of J. Alfred Fabro, M.D.

After discussion, it was VOTED to rescind the past action of the Council on 10/18/79 to conduct a poll of membership to determine if some members did not wish to continue receiving *Connecticut Medicine.*

Life Members

It was VOTED to accept for information the following list of Life Members:

Roy N. Barnett, Westport (F) - 1/1/80
Rocco Cassone, Stamford (F) - 1/1/80
Mario G. Conte, New Haven (NH) - 1/1/80
William H. Curley, Bridgeport (F) - 1/1/80
Paul E. Kaunitz, Westport (F) - 1/1/80
Frank E. Lach, New Haven (NH) - 1/1/80
Vincent A. Lynch, Bridgeport (F) - 1/1/80
Ward J. McFarland, New London (NL) - 1/1/80
John S. Paczabut, Stamford (F) - 1/1/80
John D. Ryan, Stamford (F) - 1/1/80
Elias Savitsky, Stamford (F) - 1/1/80
Bernard D. Svedlow, Stamford (F) - 1/1/80

N.B.:*The foregoing is a summary of the proceedings and actions of the Council on December 13, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan St, New Haven, for perusal by any interested member of the Society.*

NEW MEMBERS

FAIRFIELD COUNTY

Edward R. Berman, M.D., Ridgefield
Edward N. Brennan, M.D., Greenwich
Josephine H. Bristol, M.D., Danbury
Sheldon N. Capp, M.D., Greenwich
Robert R. Ditkoff, M.D., Norwalk
Rao S. Donepudi, M.D., Fairfield
Myroslaw J. Dragan, M.D., Stamford
Vaughn M. Dunn, M.D., Norwalk
Nirmal K. Dutta, M.D., Bridgeport
John E. Ertl, M.D., Danbury
John B. Famiglietti, M.D., Danbury
Adrian E. Flatt, M.D., Norwalk
Richard J. Garvey, M.D., Bridgeport
Donald L. King, M.D., Norwalk
Arnold B. Korval, M.D., Old Greenwich
Stephen M. Korwin, M.D., Danbury
Stanley J. Kramer, M.D., Darien
Wayne S. Levin, M.D., Bridgeport
Hilton C. Lewinsohn, M.D., Trumbull
Dorothea M. Linley, M.D., Fairfield
Lalitha Manoharan, M.D., Stamford
Philip J. McWhorter, M.D., Greenwich
Joan S. Narad, M.D., New Canaan
Mark I. Oestreicher, M.D., Bridgeport
William M. Pintauro, M.D., Darien
Richard A. Pollard, M.D., Stamford
David Romanoff, M.D., Stamford
Mahalingam Satchi, M.D., Danbury
Rajadevi A. Satchi, M.D., Danbury
Robert M. Stark, M.D., Greenwich
Evan J. Tilley, M.D., Bridgeport
Arthur S. Turetsky, M.D., Bridgeport
Myron Vinocur, M.D., Ridgefield

LITCHFIELD COUNTY

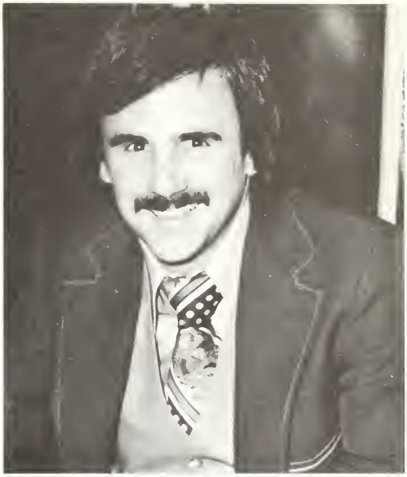
Dennis J. Arinella, M.D., Torrington
William A. Elman, M.D., Sharon
Ted B. Eshbach, M.D., Sharon
Dennis J. Gottfried, M.D., Torrington
Joel A. Markowski, M.D., Torrington
Villamor M. Parilla, M.D., Torrington
D. Hester Reik, M.D., Canton
George H. Rubin, M.D., Winsted
Jerome W. Takiff, M.D., Torrington
Orlito A. Trias, M.D., New Milford
James M. Woodruff, M.D., Sharon
Constantine Veremakis, M.D., Brookfield

MIDDLESEX COUNTY

Edward Holbrook, M.D., Middletown
Kathleen J. McShane, M.D., Colchester
Francisco J. Quintana, M.D., Middletown

NEW LONDON COUNTY

Robert S. Bell, M.D., Norwich
Alan R. Zwerner, M.D., Norwich



RICHARD J. FIORENTINO

Richard J. Fiorentino of 371 Green Hill Road, Madison, joined the Staff of Connecticut State Medical Society, October 1, 1979 as Coordinator of Special Services according to Timothy B. Norbeck, Executive Director of CSMS.

"This is a new position created by the State Medical Society to meet the increasing needs of the medical community," Norbeck said.

Mr. Fiorentino's main responsibilities will include monitoring State and Federal regulatory agencies, providing liaison services to the smaller county medical associations throughout the state and assisting in other activities of the State Medical Society.

Born in New Haven, July 11, 1947, he was educated in local schools, attended St. Anselm's College in Manchester, New Hampshire, where he received his Bachelor of Arts degree. He later was awarded a Master's Degree in Public Administration from the University of New Haven.

Mr. Fiorentino served as Information Director of the Connecticut Lung Association - South Central Branch from 1973 to 1976 and joined the Fairfield County Medical Association in 1977 as Assistant Executive Secretary. In his capacity with the Fairfield County Medical Association, he also served as Executive Secretary of the Greater Bridgeport Medical Association and the Bridgeport Dental Association.

Rick and his wife Kathy reside in Madison; their interests are tennis and jogging.

Where AMA Stands on the Issues

While some critics are quick to criticize AMA for being "negative" on health issues, the record shows that in recent years the Association has *supported,* and in several instances developed and submitted for introduction, many pieces of federal health-related legislation.

On preventive medicine . . .

Food labeling—Supported improved food labeling to aid patients in properly selecting foods as part of specified dietary regimens or in avoiding foods where a known intolerance exists.

Alcoholism—Supported the establishment and continuation of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act.

Drug Abuse—Supported the establishment and continuation of federal assistance for drug abuse education, treatment and rehabilitation programs.

Communicable diseases—Supported continuation of federal programs of immunization and control of communicable diseases and supported continuation of the Venereal Disease Control Program.

Disease prevention—Supported legislation authorizing wide-ranging efforts to reinforce programs of prevention, health promotion and health education through federal-state activities.

Family planning—Supported a program of family planning services under the Family Planning and Population Research Act.

Health education—Supported a program of federal assistance for the development and operation of health education programs at primary and secondary levels.

Mental health—Supported legislation calling for a one-year extension of the Community Mental Health Centers Act and a study of programs authorized under it, as well as legislation which would place mental health care on a par with other illnesses under federal programs.

On child care . . .

Maternal and child care and crippled children's programs—Supported continuation of Title V programs under Social Security and full appropriations for these programs.

Child immunization programs—Developed and supported legislation strengthening the present immunization program by increasing federal matching funds to states with mandatory child immunization programs.

Developmental disabilities—Supported an extension and funding of the Developmental Disabilities Act.

On medical research . . .

Cancer—Supported continuation of the National Cancer Institute and its programs.

Medical libraries—Supported continuation of assistance programs authorized under the Medical Libraries Assistance Act.

Biomedical research—Supported establishment of the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and offered suggestions for improved legislation.

Health research and statistics—Supported continuation of the National Center for Health Service Research and the National Center for Health Statistics.

On drugs and devices . . .

Labeling of drugs—Developed legislation requiring that drug containers dispensed to patients carry the name of the drug, quality and strength, except when otherwise specified by the physician.

Generic prescribing—Encouraged physicians to prescribe lower cost generic drugs when in the physician's judgment a non-brand name product would be medically appropriate, but opposed legislation mandating substitution of a cheaper generic drug by the pharmacist.

Food, Drug and Cosmetic Act amendments—Developed and supported legislation which would overhaul the nation's drug laws to improve the system for approving new drug products.

Medical devices—Supported passage of medical device safety legislation with suggestions for amendments.

Saccharin—Supported an 18-month delay in banning of saccharin to permit fuller studies and evaluation of its effects.

On physician services . . .

Emergency medical services—Supported continuation and funding of the Emergency Medical Services Act, authorizing grants to assist in establishment and operation of such systems.

Rural health care—Developed legislation establishing an Office of Rural Health within HEW and providing assistance for the development and demonstration of rural health care delivery models.

Indian health care—Supported legislation expanding health care facilities and services and educational opportunities in the health professions for Indians.

Migrant health—Supported extension of the Migrant Health Center Act program providing health services to migrant workers.

On physicians in government service . . .

Variable incentive pay—Developed and supported legislation which would make all Armed Forces medical officers eligible for special bonus pay.

Veterans Administration—Supported legislation assisting the VA to recruit medical personnel through establishment of comparable pay for all federal physicians.

National Health Service Corps—Supported legislation continuing this federal program providing physicians and other health personnel to medical shortage areas.

— Reprinted from American Medical News, June 22, 1979

Herpesviruses and Cancer

FRED RAPP, PH.D.

The evidence suggesting a causal relationship between herpesviruses and neoplasia can be divided into five categories.[1] (1) Certain animal cancers are known to be caused by herpesviruses under natural conditions. (2) Experiments in heterologous monkey hosts have demonstrated the oncogenicity of simian herpesviruses. (3) In humans, herpesvirus, herpesvirus DNA and/or herpesvirus antigens have been detected in certain cancers. In fact, the case for Epstein-Barr virus (EBV) as a causal factor in African Burkitt lymphoma satisfies Koch's postulates insofar as Koch's postulates can be satisfied for a human virus. (4) Epidemiological and serological studies of the human population provide strong supporting evidence for a previous herpesvirus infection before the development of certain cancers. (5) Lastly, *in vitro* studies unequivocally demonstrating the oncogenic potential of the human herpesviruses provide provocative supporting data for a causal relationship between herpesvirus infection and human neoplasia. The major emphasis of this paper will concern the information acquired using herpes simplex viruses as transforming agents.

A causal association between a herpesvirus and renal adenocarcinoma of the leopard frog was suggested by Lucke' in 1938. Decades later, the causative agent of Marek's disease, a lymphoproliferative disease of chickens, was identified as a herpesvirus commonly found to infect chickens. In addition, herpesviruses have been associated with lymphomas of guinea pigs and rabbits, and a herpes-like virus has been associated with lymphosarcomas of cattle. Of these naturally-occurring animal cancers caused by herpesviruses, Marek's disease and bovine lymphosarcoma have important economic consequences. A vaccine has been developed and is used routinely to protect domestic flocks of chickens from developing cancer. One vaccine in common use is a live herpesvirus isolated from wild turkeys. In a situation somewhat analogous to the cowpox-smallpox relationship in humans, the turkey herpesvirus is antigenically cross-reactive with Marek's disease herpesvirus but does not in itself cause disease. Despite considerable antigenic cross-reaction between these viruses, it was recently demonstrated that there is very little base sequence homology between turkey herpesvirus DNA and Marek's disease virus DNA.

Two monkey herpesviruses, *Herpesvirus saimiri* and *Herpesvirus ateles,* are not oncogenic in their natural hosts, the squirrel and spider monkeys, respectively, but do induce malignant lymphomas in marmosets. *Herpesvirus papio* was isolated from baboons at the Institute of Experimental Pathology and Therapy in Sukhumi, U.S.S.R. The baboon colony has a high incidence of spontaneous malignant lymphoma. The virus, which is found in the B lymphocytes of the baboons, transforms B lymphocytes of human and nonhuman primate origin and like *saimiri* and *ateles,* produces malignant lymphoma when injected into marmosets. The recent report of Neubauer and his colleagues[2] in the United States fully describes the antibody responses of baboons in the Sukhumi colony to *Herpesvirus papio* and reveals a disease relationship that is compatible with the virus as a factor in the cause of the malignant lymphoma.

Herpesvirus papio of baboons and EBV of humans are closely related viruses. They have cross-reacting antigens, DNA homology, and the ability to transform B lymphocytes of a variety of primate species. EBV has been strongly associated with two human cancers, African Burkitt lymphoma and nasopharyngeal carcinoma. It was first isolated from a biopsy specimen taken from a child with Burkitt lymphoma; it transforms human B lymphocytes into continuously growing cell lines. Burkitt lymphoma patients have higher levels of antibodies against a wide range of EBV-determined antigens than matched controls. Epstein-Barr virus-determined nuclear antigen and EBV DNA have consistently been detected in Burkitt lymphoma tissue

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FRED RAPP, PH.D., Professor and Chairman, Department of Microbiology; Director, Specialized Cancer Research Center, The Pennsylvania State University College of Medicine, Hershey, PA.

and EBV RNA has recently been detected in Burkitt lymphoma tumor tissue. Epstein-Barr virus DNA has also been found in an integrated state in EBV-transformed human cell lines. The World Health Organization sponsored a prospective seroepidemiological study on Burkitt lymphoma in Uganda. The recently published findings strongly support a causal relationship between Epstein-Barr virus and Burkitt lymphoma.[3] In terms of Koch's postulates, EBV causes malignant disease when inoculated into nonhuman primates and can be reisolated from the diseased animal. These experiments come as close to fulfilling Koch's postulates as moral testing of an oncogenic human virus will allow.

Analogous evidence for the involvement of herpes simplex viruses (HSV) and cytomegalovirus (CMV) in human cancer is less complete. The association of these viruses with the human genital tract is well documented; these viruses have been isolated from normal female and male genital organs as well as from cervical cancer biopsies.[4] Herpes simplex virus type 2 (HSV-2) and CMV antigens have been observed in cervical cancer cells. In molecular hybridization studies with human cervical tumors, a fragment of HSV DNA has been detected, implying that only a portion of the virus genome is present and transcribed in the malignant cells. There are sporadic reports that sera from cervical cancer patients react with a soluble antigen prepared from HSV-infected cells and with antigens isolated from HSV-transformed cells.

Seroepidemiological and virologic evidence have also implied an association between cytomegalovirus and a rare form of human neoplasia, Kaposi sarcoma.[5] Five cell lines established from skin lesions of patients with Kaposi sarcoma contained herpesvirus-like particles and CMV-like intranuclear inclusions. Extracts of these cells contained a common virus-specific soluble precipitating antigen. In addition, patients with European Kaposi sarcoma possessed elevated CMV-neutralizing and complement-fixing antibody in their sera.

Strong epidemiological evidence published by numerous investigators[6 7] suggests that HSV-2 may be a venereally transmitted etiologic agent for cervical cancer. Results of these investigations reveal differences in the patterns of HSV-2 neutralizing antibodies in women with cervical cancer compared to controls. The summation of these studies is that prior virus infection may be one prerequisite step in the development of cervical cancer and that early exposure, often soon after the onset of puberty, increases the risk to the neoplastic disease.

Seroepidemiological studies have provided preliminary evidence suggesting that CMV may also play a role in human neoplasia. Some cell lines derived from human prostatic carcinomas contained virus-specific membrane antigens as well as altered growth characteristics. In addition, prostate and bladder cancer patients possess elevated humoral and specific cell-mediated immunity to CMV antigens or CMV-transformed cells.[8] However, the epidemiological studies attempting to relate this virus and human cancer are still too preliminary for a general conclusion. Cytomegalovirus does possess biological properties *in vitro* that are compatible with viruses with oncogenic potential. It has the ability to induce synthesis of host cell DNA, RNA, and host proteins. Studies have demonstrated increased mitotic activity in cytomegalovirus-infected cells as well as the ability of infected fibroblasts to replicate to a limited degree in agarose.

The final evidence supporting an etiologic role for herpesviruses in human neoplasia is the demonstration, first made in this laboratory,[9 10 11] of *in vitro* transformation of mammalian cells by herpes simplex virus and cytomegalovirus. Ultraviolet-irradiated herpes simplex virus types 1 and 2 induced oncogenic transformation of hamster embryo fibroblast cells. Non-inactivated virus has been reported to transform human embryo lung fibroblast cells incubated at high temperatures. Hamster embryo lung fibroblast cells have been transformed with irradiated human cytomegalovirus and with non-inactivated virus. We also reported the oncogenic transformation of human embryo lung fibroblast cells after persistent infection of the cell culture with a prostatic isolate of cytomegalovirus. These transformed human cells induced poorly differentiated malignant tumors in athymic nude mice.

Summary

The evidence, particularly the analogy to animal herpesvirus-caused cancer, the epidemiological association of prior infection with herpesviruses with the development of Burkitt lymphoma and of cervical cancer in humans, and *in vitro* transformation studies with these viruses make an irresistible case for the involvement of herpesviruses in the initiation of certain human cancers. It is, therefore, of paramount importance to study the transformation of cells by herpesviruses to understand the similarities and differences between these viruses and other well-studied tumor viruses. Hopefully, such studies will clarify the relationship of these viruses with human cancer and aid in understanding the pathogenesis of disease. This should lead to better treatment and possibly the prevention of some human cancers.

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Doxorubicin (Adriamycin) Cardiotoxicity

MARK R. WEISBURST, M.D., EUGENE S. PEARLMAN, M.D.,
AND ROBERT J. CAPONE, M.D.

Doxorubicin (Adriamycin) an anthracycline antibiotic, has had widespread application in cancer chemotherapy. The main limitation to its use has been its potential cardiotoxicity. Clinically, this cardiotoxicity may manifest itself as fulminant congestive heart failure which may be refractory to medical treatment and may occur as long as 23 months after the last dose of the drug has been given. Although dosage schedules may play a role in the development of cardiomyopathy, the single most important factor in anthracycline-induced congestive heart failure is the cumulative dose. Progressive morphologic changes consisting of myofibrillar dropout and cytoplasmic vacuolization have been observed on endomyocardial biopsies at increasing adriamycin cumulative dosages. In order to decrease the risk of doxorubicin-induced cardiomyopathy, it has been recommended that the total dose of the drug be kept below 550 mg/m.

TABLE I

POTENTIATING FACTORS IN THE INDUCTION OF DOXORUBICIN RELATED CARDIOMYOPATHY

Cumulative Dose
Mediastinal Radiation
Concurrent Therapy with Cyclophosphamide, Actinomycin D, Mithramycin, or Mitomycin C
Age over 70
Uncontrolled Hypertension
Previous Myocardial Infarction

Unfortunately, numerous factors (Table I) may potentiate the cardiotoxicity of doxorubinin and lower the "safe" dose. In addition, there have been reports of clinically significant anthracycline cardiotoxicity at cumulative dosages of less than 30 mg/m. This "early" anthracycline cardiotoxicity may present with pericarditis-myocarditis, left ventricular dysfunction, arrhythmias, myocardial infarction, and sudden death. Histopathologic evidence of myocyte damage has been a frequent finding at cumulative dosages of less than 250 mg/m. Cardiac dysrhythmias, including ventricular tachycardia, atrial fibrillation, and atrioventricular block have followed the administration of doxorubicin in dogs. Hypotension and sinus tachycardia occur immediately after infusion of doxorubicin in dogs. A sudden fall in blood pressure could have disastrous consequences in the patient with coronary artery disease. Sudden death and myocardial infarction have both been reported following doxorubicin infusion in patients with autopsy-proven coronary artery disease.

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EUGENE S. PEARLMAN, M.D., Senior Resident in Pathology, Department of Pathology, Rhode Island Hospital.

ROBERT J. CAPONE, M.D., Director of Coronary Care, Rhode Island Hospital; Assistant Professor of Medicine, Brown University; and a teaching scholar of the American Heart Association.

Reprint requests to: 100 Retreat Avenue, Suite 806, Hartford, CT 06106 (Dr. Weisburst).

Radionuclide angiography has revealed that a precipitous fall in the ejection fraction may occur in the 24-hour period following the infusion of 60 mg/m^2 of doxorubicin.

Clearly, a method to safely monitor the administration of doxorubicin would be most desirable. Each of the available methods (Table II) has significant limitations. No technique has been able to predict which patients will develop manifestations of early anthracycline cardiotoxicity such as arrhythmias and myocarditis-pericarditis. A greater than 30% reduction in limb lead voltage on the electrocardiogram (ECG) during doxorubicin therapy has occurred in association with the development of clinical congestive heart failure.

TABLE II

METHODS USED FOR CARDIAC MONITORING DURING DOXORUBICIN THERAPY

Electrocardiography
Systolic Time Intervals
Echocardiography
Endomyocardial biopsy with right heart catheterization
Technetium pyrophosphate myocardial imaging
Radionuclide angiography

A similar decrease in ECG voltage following doxorubicin administration has been associated with a loss of cardiac muscle mass in the rat. Such a loss of ECG voltage is a late manifestation of doxorubicin-induced cardiomyopathy. In addition, low voltage in the limb leads on ECG is a nonspecific finding which can be seen in such diverse settings as malignant pericardial effusion and amyloid infiltration of the myocardium. Prolongation of the ratio between the pre-ejection period and the left ventricular ejection time has been associated with doxorubicin-induced left ventricular dysfunction. Although the measurement of systolic time intervals is simple and non-invasive, a normal result does not exclude the subsequent development of a congestive cardiomyopathy. Furthermore, systolic time intervals represent an indirect method of measuring left ventricular function which may be altered by such factors as fever, anemia, and dehydration. Endomyocardial biopsy during right heart catheterization is a sensitive technique for detecting doxorubicin cardiotoxicity, but presently has limited clinical application because of its cost and potential complications. Diffuse accumulation of technetium pyrophosphate in the myocardium may reflect myocyte damage before left ventricular functional derangement is manifested clinically. Its future role in monitoring patients receiving doxorubicin remains to be defined. More promising has been the demonstration that left ventricular function determined from echocardiography and radionuclide angiocardiography can be sucessfully used to monitor left ventricular function during doxorubicin therapy. Both techniques are considered sensitive and easily performed, and have shown a progressive decline in left ventricular ejection fraction with increasing cumulative doxorubicin dosage. Neither technique has, however, been shown to be clearly superior to the other in determining ejection fraction when uniform left ventricular wall motion is present.

Rhode Island Hospital Experience

Because of its sensitivity, and the ease of serial studies, echocardiography has been used to follow all patients treated with doxorubicin at the Rhode Island Hospital since July 1977. Other studies, including ECG, systolic time intervals, and periodic chest x-rays were also done routinely. Eighty-one patients were followed for the period July 1977-June 1978. Fifty-eight patients received less than 300 mg/m,^{2} 20 patients received 300 to 500 mg/m,^{2} and 3 patients received greater than 500 mg/m.^{2} Left ventricular dysfunction was defined echocardiographically as either a percent shortening fraction (left ventricular diastolic dimension minus left ventricular systolic dimension divided by left ventricular diastolic dimension × 100) of less than 28% or a separation between the anterior leaflet of the mitral valve and the posterior surface of the interventricular septum of greater than 10 mm (this later measurement has been shown in the absence of mitral stenosis or aortic regurgitation to correlate well with a reduced left ventricular ejection fraction). Using these criteria, 5 patients developed evidence of left ventricular dysfunction during the study period. The clinical features of these patients are described in Table III. The echocardiogram of a fourteen-year-old girl treated with a total of 450 mg/m^2 for osteogenic sarcoma is shown in Figures 1 and 2. Both the interventricular septum and left ventricular posterior wall exhibit hypodynamic wall motion. In addition, the septum is thin and does not thicken normally in systole, probably indicating a loss of functioning contractile cardiac muscle tissue. Echocardiogram done prior to the initiation of doxorubicin therapy was normal.

In all 5 patients, doxorubicin was stopped at the first indication of myocardial dysfunction. JW has had complete remission of all symptoms of congestive heart failure and had return of cardiac size to normal; CR remains mildly symptomatic on digitalis. The remaining 3 patients have not developed evidence of heart failure or myocardial dysfunction.

Fifteen patients died of complications of their malignancies during the study period, while no patient died of congestive heart failure. Additional doxorubicin was "safely" administered to two patients with dyspnea when their echocardiograms did not show evidence of left ventricular dysfunction. In our experience, the echocardiogram was useful in (1) detecting the presence of left ventricular dysfunction so that dox-

TABLE III

Pt	*Age*	*Diagnosis*	*Medistinal Radiation*	*Drugs**	*Clin Chf*	*Date*^{xx}	*Dox Dose (mg/M^2)*	*EKG*	*X-Ray*$^{+}$	*Echo*
JW	14	Osteogenic sarcoma left leg	no	VCR MTX	Mild S.O.B (1/78)	3/77 1/78	0 450	Neg T flattening	0 Vascular congestion Heart enl.	Normal LV dysf.
JF	57	Fibrosarcoma (Rt. foot) metastic to lung	no	0	no	7/77	534	Neg	0	LV dysf.
RP	57	Undif. Ca. lung	yes (12/76)	Cis-Pl	no	7/77 11/77	380 420	Neg Neg	0 0	Normal LV dysf.
CR	61	Adenocarc. (breast) metast. to ribs	yes (1966)	0	pulm edema (6/78)	9/77 6/78	220 595	NST NST	0 Heart enl. Lungs congested	Normal LV dysf. Ao Valve nl
LC	67	Oat Cell Ca. lung	yes (7/77 & 9/77)	Cis-Pl	no	6/77 4/78	0 427	Neg Neg	0 0	Normal LV dysf.

Abbreviations:

Cis-Pl = Cis-platinum
Clin CHF = Clinical evidence of heart failure
DOX = doxorubicin (Adriamycin)
0 = Heart & pulmonary vasculature normal
LV dysf. = Left ventricular dysfunction
NST = Non-specific ST segment changes
MTX = Methotrexate
VCR = Vincristine
+ = Ht size & lung vasculature
* = Other than doxorubicin
^{xx} = Includes date of first abnormal echocardiogram performed as well as date of any preceding echocardiogram.

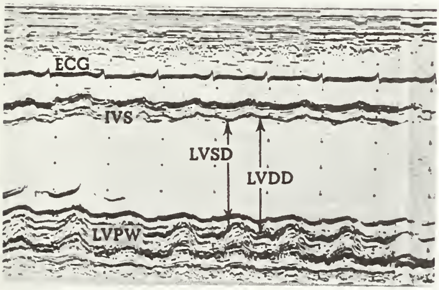

Figure 1

Echocardiogram at the level of the body of the left ventricle in a 14 year old girl with osteogenic sarcoma who developed congestive heart failure after receiving a total dose of 450 mg/M^2 of doxorubicin. The percent shortening fraction is less than 15% (see text for details).

Abbreviations:

ECG = electrocardiogram
IVS = interventricular septum
LVSD = left ventricular systolic diameter
LVDD = left ventricular diastolic diameter
LVPW = left ventricular posterior wall

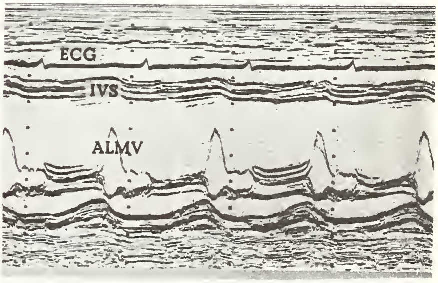

Figure 2

Echocardiogram at the level of the mitral valve in the same patient as Figure 1. The separation between the anterior leaflet of the mitral valve and the interventricular septum is 11 mm. This finding correlates with a low left ventricular ejection fraction.

Abbreviations:

ECG = electrocardiogram
IVS = interventricular septum
ALMV = anterior leaflet of mitral valve

orubicin therapy could be discontinued prior to the onset of irreversible congestive heart failure and (2) excluding the presence of a cardiomyopathic left ventricle in patients experiencing dyspnea so that additional drug could be given. With increasing doxorubicin cumulative dosage, we have noted a high frequency of left ventricular dysfunction on echocardiogram (Figure 3).

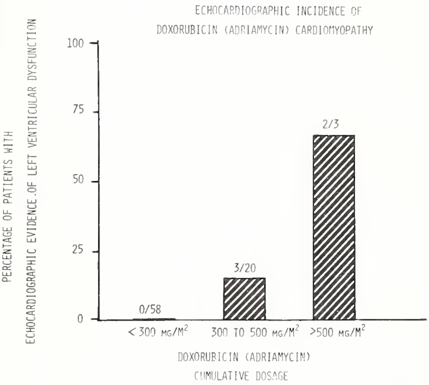

Figure 3

Graph illustrating the increased incidence of doxorubicin-induced cardiomyopathy on echocardiogram with increasing doxorubicin cumulative dosage.

Etiologic Considerations

The chemical structure of doxorubicin and its analouge daunomycin are shown in Figure 4. The anthracycline antibiotics intercalate with DNA strands with intracellular localization to the nucleus. Although the exact nature of DNA-anthracycline binding is not known, the free amino group of the sugar moiety seems to play an important role since its removal by acetylation considerably impairs the affinity of daunomycin for DNA. The resultant inhibition of DNA-RNA binding may lead to impaired protein synthesis and myofibrillar loss.

Mitochondrial disruption has been a prominent feature on electron microscopy of myocardial cells from patients who have died from doxorubicin-induced congestive heart failure. Two mechanisms may underlie this morphologic change. First, doxorubicin causes peroxidation of lipid membranes, an effect which can be blocked at *a*-tocopherol and is independent of its anti-tumor effects. Second, ubiquinone (coenzyme Q) resembles the quinone hydroquinone structure of the aglycone portion of doxorubicin (Figure 4). This close resemblance in molecular structure may lead to an inhibition by doxorubicin of the biosynthesis of coenzyme Q-10. Oral administration of coenzyme Q-10 may prevent the development of doxorubicin cardiotoxicity in man.

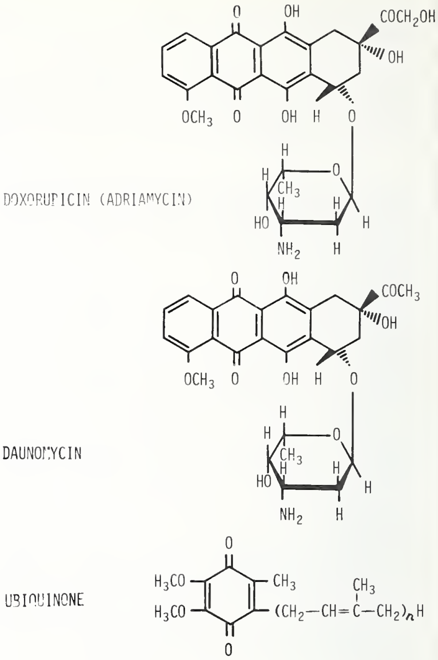

Figure 4

Molecular structures of doxorubicin, daunomycin, and ubiquinone. Note similarity between ubiquinone (coenzyme Q) and the quinone-hydroquinone ring structure of doxorubicin and daunomycin.

Conclusion

Doxorubicin-induced cardiac injury probably begins with the first dose of the drug and is cumulative. Its cardiotoxicity may relate to a combination of actions involving DNA bindings, lipid peroxidation, and interference with synthesis of mitochondrial enzymes. Amelioration of its cardiotoxic effects may evolve from altering its molecular structure, preventing its oxidizing action on lipid membranes and restoring depleted intracellular coenzymes. Sensitive non-invasive clinical tools including echocardiography and radionuclide angiography are now available to detect subtle left ventricular dysfunction and enable discontinuation of doxorubicin before the development of irreversible congestive heart failure. Additional anticipated benefits may include identification of those patients who can be safely given dosages above the recommended maximum.

Nonproprietary Name and
Trademark of Drug

Doxorubicin hydrochloride — *Adriamycin*

(References are available from the author on request.)

Invasive Pulmonary Aspergillosis after Carcinoma of Colon: Report of a Successfully Treated Case

GEORGE T. KISS, M.D., KRISHNA RAO, M.D. AND NIRANJANA RAJU, M.D.

ABSTRACT—A successfully treated case of diffuse invasive pulmonary aspergillosis is described. This illness followed colectomy for adenocarcinoma, an associated splenectomy, a course of 5-fluorouracil, and corticosteroids for concurrent pseudotumor cerebri. The aspergillosis responded to a course of three grams amphotericin-B. Further complications included preexisting ulcerative colitis, and acid fast staining organisms in lung tissue.

Although the spores of Aspergillus fumigatus and Aspergillus niger are ubiquitous in nature, three distinct clinical expressions of human infection are known. Most commonly, broncho-Pulmonary aspergillosis occurs in atopic subjects producing bronchospasm mediated by IgE, sometimes also by IgG. Mycelial growth in the bronchi may also produce tissue damage leading to concentric bronchiectasis. Mycetomas, another entity, grow in preexisting lung cavities and are usually otherwise inactive. Invasive pulmonary aspergillosis, on the other hand, occurs in the immune suppressed host. This spectrum of aspergillus in hospital cases is well described.[1] The following report is of a successfully treated case of diffuse invasive disease occurring in a young man with ulcerative colitis who was treated for adenocarcinoma of the colon.

Case Report

This thirty-six-year-old white male executive was admitted on May 13, 1978 because of headache and papilledema. There had been a sixteen-year history of ulcerative colitis complicated recently by adenocarcinoma of the colon, stage Dukes "C" for which a subtotal colectomy with ileoleoproctostomy and incidental splenectomy were performed on April 4, 1978. Workup for papilledema including C.T. scan, brain scan, carotid angiograms and lumbar puncture, was unrevealing except for markedly increased cerebrospinal fluid pressure. A diagnosis of pseudotumor cerebri

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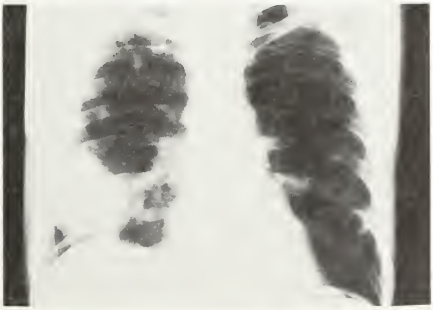

Figure 1A
Admission Chest X-ray, PA

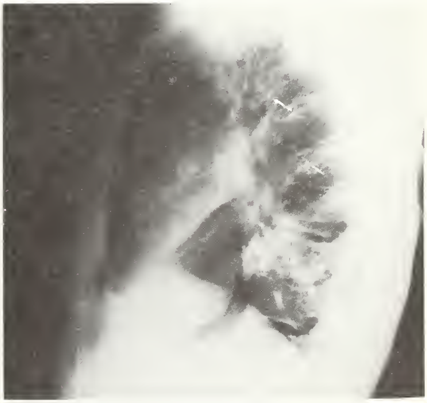

Figure 1B
Admission Chest X-ray, Lateral

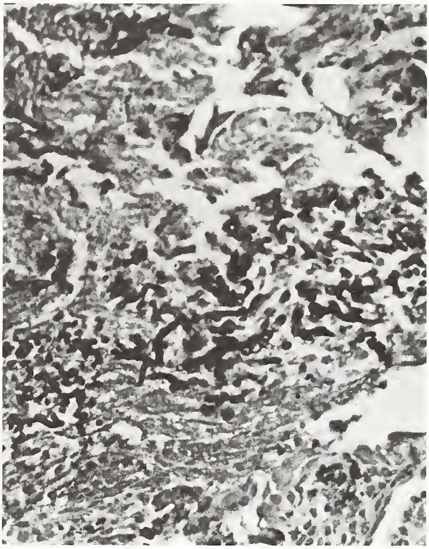

Figure 2A
Aspergillus Hyphae in Lung Tissue

was made and he was discharged on decadron 16 mgm daily and also received a two-week course of 5-fluorouracil totaling 3.75 grams.

The patient was readmitted on June 20, 1978 because of hemoptysis, pleuritic chest pain and irrational behavior for several days, having abruptly stopped decadron. Additional history included tuberculosis contact and a positive P.P.D. in 1969, for which medication was taken for three months. The patient now was acutely ill, with a temperature of 100°F, and psychotic. There were macules and pustules on the skin of the arms, legs and trunk. Bilateral papilledema was still present. There were dulness and crackles over the right lung base. A healing operative scar was noted on the abdomen.

The hemoglobin was 13G, W.B.C. 9,400 rising steadily to 24,600 with marked shift to left. X-ray of the chest revealed diffuse bilateral cavitating infiltrates (Figures 1A and 1B). Initial sputum smears showed gram positive cocci, many polys, but no acid fast organisms or fungi. Sputum cultures were unremarkable. Skin lesion cultures grew staphylococcus aureus; blood cultures were negative. P.P.D. and skin tests for candida and trichophyton were non reactive. Liver scan was normal. Treatment initially with oxacillin, and then streptomycin, isoniazid, and ethambutal were started without apparent benefit. An open biopsy of the right lung was performed on the fifth hospital day. Tissues revealed invasive aspergillosis and a few clumps of acid fast staining organisms without granulomata. (Figures 2A and 2B) Amphotericin B was begun increasing daily dose by 5 mgm until reaching 50 mgm, and isoniazid was continued. After starting treatment several sputum cultures returned positive for Aspergillus fumigatus. The patient improved symptomatically after several days and continued to do so. Amphotericin was maintained 70 mgm/day three times weekly on an outpatient basis for a total of 3 Grams. During this period the patient became entirely asymptomatic, papilledema subsided, chest x-ray (Figures 3A and 3B) cleared significantly, and usual activities were resumed.

Discussion

Patients with neoplastic disease have been shown to be highly susceptible to infections with a wide variety of otherwise innocuous agents. These include the spectrum of gram negative bacteria, acid fast organisms, viral proliferation, as well as fungal invasions.[2] In two extensive studies of one hundred and ninety-one aspergillosis cases the great majority occurred in hematologic or lymphoreticular disorders.[3 4] Of the few cases in solid tumors, one or two were reported after carcinoma of lung, breast, bladder, ovary, vagina, and three after prostate. These cases were similar to the leukemia or lymphoma patients in that they each had in common at least two of the following factors: corticosteroid therapy, cytotoxic agents, or leukopenia. Prognosis was generally poor being related to the status of the underling disease.

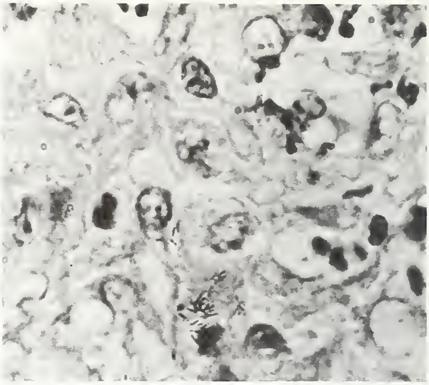

Figure 2B
Acid Fast Organisms in Lung Tissue

Our case was a young male immunosuppressed by chronic ulcerative colitis and supervening adenocarcinoma of the colon, for which a bowel resection, and for technical reasons, splenectomy were performed. It is difficult to speculate about the predisposing factors. The ulcerative colitis had been stable prior to the development of adenocarcinoma of the colon. Surgery had been difficult with extensive lymph node dissection and splenectomy. Large doses of corticosteroids were started one month post-operatively because of increased intracranial pressure. Steroids are known to depress T lymphocyte response which may have contributed to the fungal infection. Two months post-operatively 3.7 G of 5-fluorouracil had been given because of the bowel tumor.

It is well established that patients with splenectomy are more prone to overwhelming infections with polysaccharide coated bacteria, such as H. influenza, type b, pneumococcus, and meningococcus. Although decreased opsonization is suspected to have a role, the exact reason is not established.[8] Search of the world literature, however, fails to reveal any mechanism for increased fungal disease after splenectomy.

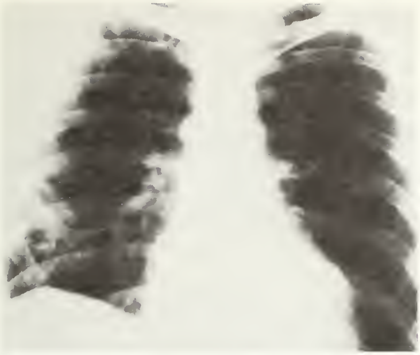

Figure 3A
Post treatment X-ray, PA

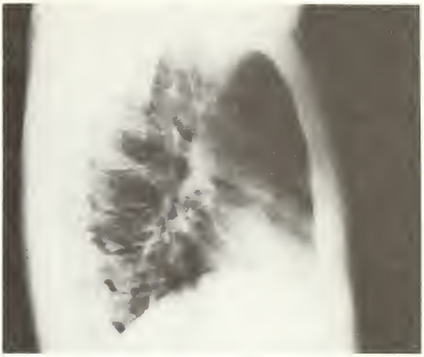

Figure 3B
Post treatment X-ray, Lateral

Invasive pulmonary aspergillosis presented as acute fever and hemoptysis two weeks later. The admission chest x-ray was consistent with diffuse necrotizing bronchopneumonia and cavitation (Figure 1) although one month previously film had been clear.

Differential diagnosis included staphylococcal abscesses, fungal disease, mycobacterial infection, multiple infarctions, and less likely, diffuse metastasis. Because of the clinical urgency, diffuse parenchymal involvement, and the uncooperative status of the patient, an open lung biopsy was proceded directly. The biopsy specimen revealed extensive invasion of lung parenchyma and vessels by aspergillus as well as the presence of a few clumps of acid fast organisms without granulomatous reactions (Figure 2) Subsequently several sputum cultures grew Aspergillus fumigatus. The mycobacteria were considered inactive.

Isoniazid was maintained and a course of amphotericin-B was initiated gradually increasing the daily dosage to 70 mgm.[5] Within a few days there was decrease in fever, cough and leukocytosis, with simultaneous increase in appetite and well being. Amphotericin was continued 70 mgm three times weekly[6] on an outpatient basis until a total of 3.0 G were given. By this time there was significant radiographic resolution and the patient had resumed his usual home and work routine. Recurring thrombophlebitis at intravenous sites was controlled by using a twenty-five gauge pediatric needle. Transfusion of two units of packed red cells was given when the hemoglobin fell below 9G. Intravenous hydrocortisone (25 mgm) was given prior to each treatment to minimize adverse systemic reactions. The BUN did not exceed 30 mgm during the course of treatment.

The cause of the increased intracranial pressure which occurred could not be explained. Improvement began with corticosteroid therapy, but continued with the course of amphotericin. The psychotic reaction was thought to be steroid induced.

This case of invasive pulmonary aspergillosis is presented because of the successful outcome despite extensive disease. The value of early diagnosis and treatment is stressed. If necessary an open lung biopsy should be performed. Favorable factors were the absence of demonstrable metastatic neoplasm, sufficient leukocyte response, adequate nutrition and youth.

Summary

A case of invasive pulmonary aspergillosis following colon resection for carcinoma is described. Underlying conditions were chronic ulcerative colitis, splenectomy, and therapy with corticosteroids and 5-fluorouracil. Factors associated with a good clinical response to amphotericin B are considered.

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Mucinous Cystadenocarcinoma of Retroperitoneum

MARC P. STORCH, M.D. AND UMA RAGHAVAN, M.D.

ABSTRACT—Primary retroperitoneal borderline mucinous cystadenocarcinoma is exceedingly rare. Such a case is described.

A seventeen-year-old white female was found to have a large abdominal mass on routine exam. Workup included an ultrasound diagnosis of ovarian cystadenocarcinoma. At laparotomy a large multiloculated cyst arising from the retroperitoneum was found at the right pelvic brim. The mass weighed 820 grams and measured 17 x 14 x 6 centimeters. Microscopic exam revealed a Grade I mucinous cystadenocarcinoma. In view of the normal ovaries identified in this case, it seems possible that this tumor arose from a supernumerary ovary.

Primary retroperitoneal borderline mucinous cystadenocarcinoma is exceedingly rare. Only one case has been described[1] previously. The following case report describes such a tumor found unexpectedly at the time of exploratory laparotomy.

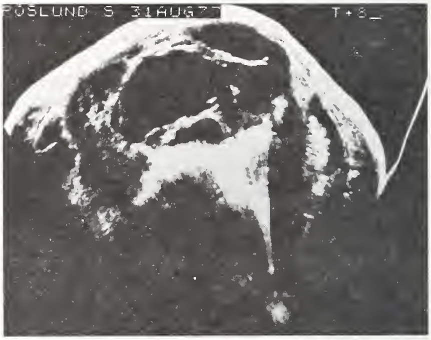

Figure 1

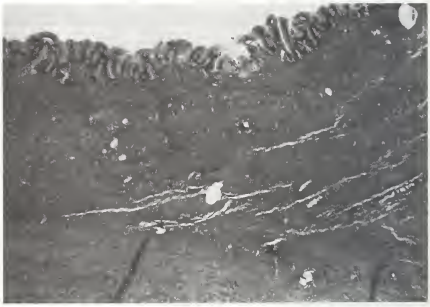

Figure 2

Case Report

A seventeen-year-old white female was found to have a large abdominal mass on routine pre-college examination. Physical examination was normal except for a cystic mass extending three fingerbreadths above the umbilicus. Radiologic evaluation included intravenous pyelogram which showed the bladder displaced inferiorly with mild bilateral hydronephrosis and barium enema revealing displacement of the cecum.

Ultrasonography (Figure 1) showed a large multiloculated cystic mass arising out of the pelvis with ascites, consistent with appearance of ovarian cystadenocarcinoma.

At laparotomy, a large multiloculated cyst arising from the retroperitoneum at the right pelvic brim was found. The mass was unattached to any retroperitoneal structures and was in close proximity to the right ureter. The uterus, both ovaries and uterine tubes were normal. The mass removed intact weighed 820 grams and measured 17 x 14 x 6 centimeters.

The external surface of the cyst was lobulated and smooth; its wall 1.5 centimeters in thickness. The locules varied from 1-7 centimeters in diameter and contained tenacious dark gray colored fluid.

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Microscopic examination (Figure 2) revealed a Grade I mucinous cystadenocarcinoma with a fibrous wall of collagen and fibroblasts. The epithelial cells were tall columnar with areas of stratification showing nuclear atypia with occasional mitotic figures. There were a number of glands in the supporting stroma but no ovarian tissue was identified. There was no evidence of a retroperitoneal teratoma.

The patient's post-operative course was unremarkable except for a temperature spike which responded to antibiotics. She was admitted five months later for excision of a right breast mass which revealed sclerosing adenosis. Regular follow-up for the past year and a half including pelvic exam, ultrasound and intravenous pyelogram have been normal. The patient has been on a course of Cytoxan, 100 milligrams a day during this time, and will be continued for a total of two years.

Discussion

Retroperitoneal tumors of ovarian type are rare. Several mucinous type tumors have been described.[2,3] One possible origin for this tumor is invagination of mesothelium with subsequent metaplasia. The multipotentiality of the peritoneal mesothelium could easily account for the histogenesis of this type of tumor. It is thought that some of these tumors arise from supernumerary ovaries.[4,5] In view of the normal ovaries identified in this case, it is possible that this tumor arose from a supernumerary ovary. Normal ovarian tissue was probably completely replaced in this case because of the size of the tumor.

This is believed to be the first case report of a mucinous cystadenocarcinoma of the retroperitoneum of the borderline variety.

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Addendum

The patient was followed regularly (every three to four months) with pelvic exams and ultrasound. Twenty-one months after her initial surgery and the start of Cytoxan, a fullness was noted to the left and posterior to the uterus. Ultrasound confirmed a 3 x 4 x 8 centimeter fluid collection. At laparotomy a seven centimeter left para-ovarian cyst was removed. The pathology was identical to her previous retroperitoneal tumor. Wedge biopsies of both ovaries were performed and showed normal ovary. Cell blocks of the peritoneal fluid were negative for malignancy. The rest of the abdominal exploration including the right retroperitoneal space was completely normal. A pea sized mass resembling ovarian tissue was removed from the right mesosalpinx in the corresponding position where the left para-ovarian cyst originated. This tissue did resemble ovarian stroma. The likelihood that these tumors are originating from small ectopic ovaries seems great.

Federal Trade Commission vs. Michigan State Medical Society

The Federal Trade Commission has accused the Michigan State Medical Society with price-fixing and restraining fee competition among doctors in Michigan.

According to an FTC news release, the agency is charging that the Medical Society organized an effort to try to get its 8,700 members to stop doing business with the Michigan Blue Cross and Blue Shield Plan "in order to influence Blue Shield reimbursement and cost containment policies."

The complaint alleges that the Society "solicited proxies from its members to authorize termination if (the) Blue Shield (Plan) and Michigan Medicaid did not adopt policies acceptable to the Society."

The complaint charges the Society with conspiring to restrict, regulate, impede or interfere with the health-care cost containment or reimbursement policies of the Plan and Michigan Medicaid; engage in negotiations with the Plan with respect to its health-care cost containment or reimbursement policies; fix, stabilize or otherwise tamper with the fees Michigan physicians receive for services.

Important Advances in Clinical Medicine

Epitomes of Progress — Allergy

Rhinitis Medicamentosa

Rhinitis Medicamentosa or medication rhinitis is one of the most frequent and, unfortunately, most overlooked causes of nasal stuffiness. The discomfort to persons with this condition cannot be minimized. Eating is hampered by an inability to breathe through the nose; however, the most distressing complaint is difficulty in sleeping. It is not uncommon for patients to be awakened three to four times a night by nasal obstruction. Although patients with allergic rhinitis are more prone to develop this syndrome, it occurs frequently in the general population.

The leading cause of rhinitis medicamentosa is excessive use of topical nasal decongestants. Virtually all nose drops and sprays, whether prescription or over-the-counter preparations, contain decongestants that are sympathomimetic amines. These preparations cause vasoconstriction, diminish nasal secretion of mucus and inhibit nasal ciliary action. Initial relief following their use is dramatic; however, all produce a *rebound* congestion as vasoconstriction diminishes. With prolonged use, their effects are paradoxical—the period of a patent nasal airway becomes progressively shorter, while nasal obstruction becomes longer lasting and more severe. This leads to dependence on the spray or drops, the patient usually buying two or three bottles at a time. Because one of the important functions of the nose is humidification of the air, patients also complain of a dry mouth and, often, a sore throat. The constant interruption of sleep leads to marked irritability and depression.

Antihypertensive drugs, especially those containing reserpine (even in small amounts), guanethidine, alpha methyldopa or propranolol can trigger the same sequence of symptoms. Other drugs or substances which have been implicated as causes of rhinitis medicamentosa include acetylsalicylic acid, cocaine, and estrogens; less frequently implicated substances include cromolyn sodium, alcohol and tobacco.

Rhinitis medicamentosa should be approached as an acute as well as a chronic problem. Simple awareness will often uncover the offending medication and the underlying condition that has precipitated the symptoms. However, during the acute phase, swelling may interfere with an adequate visualization of the nasal airway. Subsequent examination may show the presence of allergic rhinitis, nasal polyps or nasal septal obstruction which can be treated. The offending medication *must* be discontinued. An explanation of the *rebound problem* is useful in obtaining a patient's cooperation. The short-term use of dexamethasone intranasal aerosol in decreasing doses for seven to ten days has been very effective in reducing inflammation of the nasal turbinates. Antihistamines and oral decongestants, because of their nonspecific drying action, tend to aggravate the condition initially, but may be useful later. Definitive therapy will depend on the underlying condition.

Daniel Gorenberg, M.D.

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Recent Findings in Atopic Dermatitis

The immunology of atopic dermatitis has received much attention in the last ten years. Clinical observations as well as *in vivo* and *in vitro* studies have suggested that immunodeficiency may be involved in the pathogenesis of atopic dermatitis. An uncontrolled clinical study suggested that atopic dermatitis could be dramatically improved by levamisole, an anthelmintic and known immunostimulant. Two randomized, double-blind studies in children and adults failed to show any improvement in atopic dermatitis in the levamisole-treated groups.

We have examined the *in vitro* effect of levamisole on lymphocytes, neutrophils, basophils and platelets from patients with atopic dermatitis and levels of serum IgE greater than 1,000 IU per ml. Levamisole had no effect on basophil histamine release, platelet serotonin release, neutrophil chemotaxis and phagocytosis, T cell number and lymphocyte mitogenesis induced by phytohemagglutinin, concanavalin A or pokeweed mitogen. Thus, levamisole appears not to have any *in vivo* or *in vitro* value in atopic dermatitis.

Elevated serum levels of IgE remain the most consistent immunologic abnormality in this disease and understanding its regulation may be important for future therapeutic advances. Studies have shown that a small subpopulation of human lymphocytes have surface receptors for the constant function (Fc) portion of IgE. The function of these IgE-Fc receptor lymphocytes and their relationship to grossly elevated IgE levels in atopic dermatitis patients is now being investigated.

Regulatlion of IgE by helper and suppressor cells or soluble factors (or both) is another area under investigation. However, clinicians should continue to rely on current conventional therapy of atopic dermatitis until new approaches are confirmed and made available.

Richard O'Connor, M.D.
Robert N. Hamburger, M.D.

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Indications for Use of Beclomethasone Dipropionate (Vanceril)

Beclomethasone Dipropionate (Vanceril) is an inhalable synthetic corticosteroid useful in the control of chronic bronchial asthma. It apparently works by direct contact and is nearly insoluble with little systemic absorption. Sparing patients from systemic side-effects represents a great advance in management of the disease. When taken in its recommended dosage, it appears to cause no adrenal suppression or growth retardation in children.

At present, use of Vanceril in treating asthma is limited to selected patients whose conditions cannot be controlled with bronchodilators and other nonsteroid medications and patients with chronic severe asthma already dependent on systemic steroid therapy. Its use is not indicated in the treatment of status asthmaticus or acute asthmatic attacks.

During and after transfer from systemic corticosteroids to aerosol beclomethasone dipropionate, adrenal insufficiency has been reported. This can be obviated by warning the patient that during exposure to stressful situations such as trauma, surgical procedures or uncontrollable asthma, administration of systemic steroids should be resumed. Risk of adrenal insufficiency can be assessed with early morning resting cortisol levels and response to adrenocorticotropic hormone.

Other side-effects of Vanceril therapy include monilial infections of the mouth and pharynx in a small percentage of patients and reappearance of allergic manifestations such as rhinitis and eczema which were previously suppressed by systemic steroid therapy. Monilial infections may require antifungal treatment with nystatin (Mycostatin) discontinuation of Vanceril therapy.

The effects of the drug in active or quiescent tuberculosis and, in particular, the long-term effects of aerosolized corticosteroids on various airway tissues remain to be determined.

Herbert L. Stein, M.D.

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Mold Control

Two sources for mold spores growing indoors have been identified. The first and, generally, more important source (exogenous) originates from outdoors but is constantly introduced into homes. The second source (endogenous) originates indoors but varies greatly from house to house. Studies in Michigan, using the volumetric Andersen sampler during frost-free periods, indicated that indoor viable mold spore counts were approximately 25 percent of the outdoor counts. Indoor mold counts varied from 10 to over 20,000 spores per cu meter. Higher indoor counts were associated with high relative humidity within the home, and generally occurred in homes with central humidification.

Similar studies done in Southern California showed a statistically significant correlation between the following outdoor characteristics and high viable mold spore counts indoors: extensive shaded areas near the house, large quantities of organic debris (fallen leaves, grass not removed after cutting, hay, compost or stands of dried weeds and grass on the lot), poor landscape maintenance and previous indoor water problems. Two indoor characteristics associated with low indoor mold isolates were the presence of a central electrostatic filtration system and compliance with dust control. In homes with continuously operated electrostatic filters, the mean viable mold spore count was 155 per cu meter, while in homes with intermittently operated units, the mean mold spore count was 344 per cu meter. In control homes the mean count was 687 spores per cu meter. A less dramatic although still statistically significant reduction in mold spore isolates occurred in homes where dust control measures were being implemented.

The effect of air-conditioning on indoor mold levels was recently studied. A statistically significant reduction in mold spore isolates occurred in the air-conditioned homes, but no differences in the percent concentration of the major genera were noted. The investigators had expected a greater percent reduction in large mold spores if these were being trapped in the air-conditioner, but no reduction in smaller spores. Because all genera were reduced equally, the investigators felt that merely closing an air-conditioned home created a barrier to the ingress of outdoor molds resulting in lower indoor mold levels. They also noted reduction of mold isolates in air-conditioned homes with low indoor relative humidity.

In appears prudent to recommend the following program to minimize indoor mold spore concentrations. The amount of shade near a house should be reduced by avoiding plants too close to the building and by periodic pruning of trees and shrubs. Better landscape maintenance with removal of all dead vegetation within 150 to 200 feet of the house would be helpful. Dust control compliance is encouraged. Water damaged items including carpet, books, wallpaper and wicker baskets should be removed from the premises and the cause of any previous water problem corrected. Properly installed and operated central electrostatic filtration should significantly reduce the amount of viable indoor mold spores. Humidification devices including cold mist vaporizers are best avoided, especially in homes of mold-sensitive persons. Logically, use of a dehumidifier in damp areas should be helpful, but no studies have yet been carried out to verify this commonly held belief.

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Perspective on Asthma in Pregnancy

There is nearly equal probability that maternal asthma will improve, remain the same or grow worse during pregnancy. Improvement tends to occur in the first trimester and deterioration in the second and third. Cases of severe steroid-dependent asthma are the most likely to cause deterioration in these women's conditions during their pregnancies. Slightly increased percentage rates of premature births, spontaneous abortions and newborn deaths resulting from maternal asthma have been noted. The greatest danger to the fetus in maternal asthma is maternal hypoxia resulting in fetal hypoxia.

Several drugs used in the treatment of asthmatic patients are contraindicated in pregnancy. Preparations containing iodine may cause congenital goiter. Tetracyclines may stain the teeth. Sedatives in general are to be avoided because of their respiratory depressant effect. Hydroxyzine in large doses has been reported teratogenic in mice. The safety of the beta agonists such as terbutaline and metaproterenol has not been established in pregnancy.

Medications considered safe in the treatment of asthma during pregnancy include theophylline, ephedrine, cromolyn, penicillin and erythromycin. Corticosteroids used in the first trimester are known to cause cleft lip, cleft palate and skeletal deformities in experimental animals. They should be avoided if bronchospasm can be controlled without their use. In pregnant women with asthma who are steroid dependent, inhaled beclomethasone may allow reduction of dosage or even cessation of use of systemic steroids, although the safety of beclomethasone in pregnancy has not been established.

Because allergy skin testing and immunotherapy carry some risk of producing anaphylaxis, they should be used with special caution in pregnant patients, but need to be excluded. Ideally, asthma management should begin well in advance of contemplated pregnancies and control of this disorder should reduce both maternal and fetal morbidity and mortality.

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Reactions to Local Anesthetic Agents

Since Freud and Koller introduced cocaine into clinical use as a local anesthetic in 1884, various effects of local anesthetic agents have been described, including toxic effects of the drugs, systemic sympathomimetic stimulation, and vasovagal, local and allergic reactions. Rarely, preservatives such as paraben or methylparaben also may be incriminated.

Appropriate diagnoses are usually readily apparent by taking detailed histories of the episodes. Toxic effects are related to the total dose administered and include central nervous system stimulation (restlessness, dizziness and disorientation) or central nervous system depression (slurred speech, respiratory failure). Systemic sympathomimetic stimulation results from inclusion of epinephrine in the local anesthetic and includes anxiety, tremor, diaphoresis and tachycardia. Vasovagal symptoms may occur as a result of an injection of a local anesthetic; these may include apprehension, hyperventilation, hysteria and syncope. Localized swelling at the injection site often occurs and may be due to a local toxic effect of the anesthetic or to the procedure itself; however, especially when severe, a local IgE-mediated phenomenon cannot be ruled out. Pruritus, rhinorrhea, urticaria, angioedema and manifestations of bronchospasm, that is, cough and wheezing, are hallmarks of an allergic reaction. On careful scrutiny, however, only a small percentage of those presenting with questionable reactions will fit this category.

The clinical approach presumes a need to use an agent for either a necessary local procedure or for treatment of a cardiac arrhythmia. The risks inherent in the alternatives—whether to use a general anesthetic or not to use a lifesaving drug—clearly warrant provocative procedures and require an understanding of the classification of local anesthetics.

Although many pharmacologic agents have local anesthetic properties, all commonly used agents have a fundamental structure consisting of three parts: an amino group linked by an intermediate group to an aromatic residue, an ester (group I), or an amide or other bond (group II) serving to differentiate the two basic groups. Prominent among those in group I are benzocaine, butacaine (Butyn), chloroprocaine (Nesacaine), procaine (Novocain) and tetracaine (Pontocaine). These compounds will cross-react with each other. Reactions to compounds within this group have been reported much more frequently than to those within group II which represent a more diverse subset that lacks the ester bond. These compounds include dibucaine (Nupercaine), lidocaine (Xylocaine), prilocaine (Citanest), mepivacaine (Carbocaine) and proparacaine (Ophthaine). At present, it is presumed that those within group II do not cross-react with each other.

If a patient clearly has had an allergic or even a moderate localized reaction to a drug, that specific drug should not be reused. Another non-cross-reacting drug should be chosen. After informed consent has been obtained and preparations made to treat any severe adverse reaction, titration intradermal skin testing may be used, with subsequent subcutaneous challenge using increasing amounts until from 0.5 to 1.0 ml is safely administered. There is disagreement as to the validity of skin testing in diagnosing or predicting immediate reactions. However, no one would disagree that it is still useful as a challenge technique. In recent studies, positive test results to anesthetics to which patients had not been previously exposed did not deter the authors from challenge, and no adverse reactions were encountered. In obvious toxic or vasovagal responses, or in reactions of questionable severity, the reuse of that agent will depend on the physician's confidence regarding the diagnosis.

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Intravenous Radiocontrast Dye Reactions

Adverse reactions to radiocontrast dyes (RCD) can range from innocuous vasomotor symptoms and rashes to life-threatening anaphylactoid reactions. The incidence of anaphylactoid reactions (any immediate reaction, whether urticaria or shock) after RCD has been reported at less than 2 percent, and the resultant mortality from one in 40,000 to one in 116,000 patients examined, or an estimated annual mortality of 500 patients. The mechanism for such reactions is unknown, but activation of the complement system, inactivation of enzyme systems, hyperosmolarity and antigen-antibody complexes have been suggested as possible explanations. The classic IgE-mediated anaphylactic mechanism has not been found. However, it is well established that RCD can release histamine both *in vivo* and in vitro from basophils and mast cells.

Initial studies using prophylactic antihistamines to avert the immediate reactions showed a decrease in the frequency and severity of reactions. More recent studies indicated that pretreatment with both steroids and antihistamines was successful in preventing serious reactions when the dyes were readministered to those who had had previous severe reactions. The risk of another anaphylactoid reaction in RCD-sensitive patients is unknown because patients may or may not react on subsequent exposure. Intravenous pretesting has been advocated to detect those patients who are at greatest risk for repeated serious reactions. However, intravenous pretesting has inherent risks, and its reliability has been disputed. Nevertheless, some practical guidelines for the management of RCD-reactive patients should be followed:

- After the physicians involved agree that the risk/benefit ratio supports the study, the patient should sign an informed consent in which the risks, options and potential benefits of the planned procedure are explained.
- Premedication with diphenhydramine (50 mg given intramuscularly) an hour before the study and prednisone (50 mg orally or equivalent parenteral dose) every six hours starting 18 hours before the procedure is indicated.
- A free-flowing intravenous line plus resuscitation equipment should be available to guard against the possibility of a serious reaction in spite of premedication.

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Asthma and Sports

Can most asthmatic youngsters participate in active sports? Yes. The attitude held by many parents, school instructors, coaches, counselors and even some physicians which prevents the asthmatic from participating in physical exercise should be changed.

Exercise-induced asthma or bronchospasm (EIA and EIB, respectively) classically occurs in a person during a rest period after exertion of at least five minutes, and may last as long as two hours. It occurs in nearly all asthmatic persons and in approximately 40 percent of those who have only allergic rhinitis or hayfever. The symptoms may include dyspnea, wheeze, chest tightness, increased mucus production, cough, choking or fatigue. Because of these restrictive symptoms persons with asthma are often told to modify their active participation in sports. Others may offer excuses to avoid exercise due to fear or anxiety.

Exercises and physical fitness programs designed to improve diaphragmatic breathing apparently do not lessen the frequency, severity or duration of exercised-induced asthma attacks. Short exercise sessions of up to three minutes, however, often result in improved pulmonary function for several minutes. Consequently, short increments of running or other exercise can be tolerated by those in whom EIA may occur.

Exercise-induced asthma occurs equally in both allergic and nonallergic asthmatic persons. Cold or dry air, and airborne irritants and allergens can increase the probability of EIA developing. Generally, EIA appears to be directly related to the amount of exercise or work done by a person.

Most studies have shown that bronchodilators prevent EIA if given beforehand. Cromolyn sodium will also modify EIA in most allergic persons. Steroids, however, in any form have no apparent effect on EIA.

EIA can be prevented with theophylline given orally or beta adrenergic drugs given either orally or by inhalation 30 minutes before exercise. Cromolyn sodium must be given about an hour before exercise to be helpful.

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Physical Agents That Mediate Urticaria

Urticaria, characterized by localized skin edema or wheals, may be caused by any of several immunologic and nonimmunologic factors. Although the cause of chronic urticaria is never found in three fourths of cases, reactions due to physical agents such as pressure (dermatographia), heat and effort (cholinergic urticaria), cold, vibration and light (solar urticaria) can be identified and appropriately treated.

Dermatographia, one of the most common types of urticaria, is sometimes due to physical allergy. In certain cases, evidence indicates that it is mediated by, and can be passively transferred with, IgE. Dermatographia often accompanies urticaria induced by other causes.

Cholinergic urticaria is precipitated by heat, emotional stress and exercise as highly pruritic wheals (1 to 3 mm in size) with erythematous flare. Intradermal injection of methacholine (1:5,000) may produce a large wheal with satellites. This test, however, is not reliable enough for routine use because there are many false-negatives and some false-positives. Release of histamine into venous blood during attacks has been shown in some but not all of these patients. Activation of the cholinergic nervous system appears to be important in causing the wheals.

Solar urticaria is relatively uncommon. Several subtypes of solar urticaria are induced by light of wavelengths extending from 250 to 460 nM, with erythema and wheals developing in patients two to three minutes after exposure to sunlight. Repeated daily increments of solar exposure may prevent attacks.

Heat urticaria is characterized by swelling, redness and temperature dependence, and is not related to sweating or exertion. The lesions are nonpruritic and indurated. The phenomenon is associated with activation of complement via the alternate complement system. A pathologic reaction at the level of the venules with vascular endothelial damage has been described, but these lesions can be controlled by avoidance of heat. There is no role for antihistamines or corticosteroids in therapy.

Vibratory urticaria consists of prompt appearance of pruritus and swelling at the site of vibratory stimulation. The reaction is histamine mediated and is adequately controlled with antihistamine and avoidance of the source of vibratory stimuli. An autosomol dominant hereditary pattern has been described.

The familial form of *cold urticaria* is characterized by autosomol dominance, fever, arthralgia, leukocytosis and burning, erythematous papules. The ice cube test is negative and cannot be passively transferred. The papules occur about 30 minutes after cold exposure. A more common, acquired form of cold urticaria is associated with a positive ice cube test in all patients. In about 50 percent of patients, the test can be passively transferred with serum to normal persons. Urticaria in these persons is not associated with fever, arthralgia or leukocytosis. Cold-induced symptoms of systemic diseases such as cryoglobulinemia, cryofibrinogenemia, syphilis, connective tissue diseases and hematologic malignancies must be ruled out. Sporadic cold urticaria is definitely associated with IgE-mediated release of histamine which can be inhibited with antihistamines. *Delayed cold urticaria* is a rare disease consisting of a painful induration occurring 12 to 24 hours after local cold exposure.

The treatment of urticaria induced by physical agents should be based primarily on removal of the cause. As with patients with other types of urticaria, these patients should be advised to minimize their exposure to alcohol, heat, acetylsalicylic acid, exertion and emotional stress. Topical agents and corticosteroids as well as attempts to desensitize patients with allergens are of no help in these situations. Appropriate sun screens may be of value in patients with solar urticaria, and antihistamines, including cyproheptadine and hydroxyzine, are of particular value in patients with dermatographia, cholinergic urticaria or cold urticaria.

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Factors That Influence Theophylline Metabolism

Many allergists in the United States consider theophylline to be the initial bronchodilator of choice. Serum levels of theophylline of 7 to 20 μg per ml are generally accepted as therapeutic. Although symptoms of toxicity may occur when the level of theophylline in the serum is in the therapeutic range, toxicity is generally associated with levels in excess of 20 μg per ml. It is incumbent on the physician using this valuable but potentially toxic drug to appreciate the number of factors that influence its biotransformation and clearance.

Body Weight

The apparent volume of distribution for theophylline is reduced in obese patients. When calculating dosage, one must use a patient's ideal weight to avoid toxicity.

Age

The dosage of theophylline required for children less than 1 year of age varies greatly. In this group, monitoring of serum levels of theophylline may be required to avoid problems with toxicity.

Children 1 to 8 years of age have average plasma clearance values above those noted for adults. The recommended oral dose for this group varies from 16 to 24 mg per kg of body weight per day. For those between 9 and 16 years of age, the recommended oral dose is 16 to 20 mg, and for adults it is 9.6 to 19 mg per kg of body weight per day.

Diet

Dietary methylxanthines, particularly caffeine, have been shown to interfere with theophylline elimination in normal persons. A decrease in theophylline elimination has also been noted in patients on high carbohydrate-low protein diets while a high protein-low carbohydrate diet increases theophylline elimination. Charcoal-broiled foods with a high polycyclic carbon content may increase the rate of theophylline biotransformation.

Diseases Altering Theophylline Metabolism

Theophylline clearance is affected by a variety of diseases involving the cardiorespiratory systems and the liver. These include congestive heart failure, acute pulmonary edema, chronic obstructive pulmonary disease, pneumonia, and cirrhosis and other hepatic diseases. Reduction in the dose of theophylline administered to these patients and careful monitoring of serum theophylline levels is required for proper management. Acute febrile illness has also been reported as a cause of transient increase in serum theophylline levels.

Smoking

In cigarette and marijuana smokers, there is a faster plasma theophylline clearance and a shorter half-life than in nonsmokers. Jusko and co-workers have shown that an additive increase in theophylline clearance occurs in those who smoke both substances.

An approximate reduction of 50 percent in theophylline clearance has been reported in patients who were receiving troleandomycin (250 mg four times daily). A similar but less pronounced effect due to erythromycin has been reported recently and appears due to reduced clearance and consequent prolonged half-life of theophylline. A reduction in theophylline dose is necessary for patients already receiving high-dose treatment when erythromycin or troleandomycin is coadministered. The possibility of other, as yet unrecognized, drug interactions with theophylline must be appreciated. If symptoms suggestive of theophylline toxicity occur, a careful review of medications being administered should be made and the theophylline kinetics studied.

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Gastroesophageal Reflux and Asthma

Respiratory manifestations of gastroesophageal (GE) reflux are increasingly being reported. In children and infants, reflux has been associated with bronchiolitis, pneumonitis and failure to thrive, while in adults bronchitis, laryngitis, bronchiectasis, atelectasis, fibrosis, pneumonia and intractable asthma are reported complications. The theories proposed to explain how GE reflux may cause or exacerbate asthma are: (1) microaspiration of gastric contents resulting in an exudative mucosal reaction, (2) vagal reflux arc from the esophagus to the lungs causing bronchoconstriction and (3) nonspecific irritant effect of microaspirates on a hyperactive bronchial airway.

The principal support of GE reflux-inducing asthma has come from reports of an increased association between hiatus hernia and asthma, and improvement of the respiratory systems following medical or surgical antireflux procedures. Unequivocal evidence that microaspiration occurs is lacking, but a recent study using a radioisotope technique showed gastropulmonary aspiration in two patients. Airway resistance increases after intraesophageal acid instillation in some asthma patients, in agreement with the vagal reflex arc theory.

GE reflux can be detected by techniques ranging from routine upper gastrointestinal series to more sensitive methods of cineradiography, esophagoscopy with biopsy, acid probe pH determination, acid perfusion study, esophageal manometry and isotope scintiscanning. University agreement on the criteria for diagnosing reflux is lacking. Further studies are needed to delineate the exact role of GE reflux in the pathophysiology of certain respiratory diseases. Until then clinicians should consider the diagnosis of GE reflux particularly in patients with recurrent pneumonitis or nocturnal asthma who also have gastrointestinal distress. Treatment is directed against factors that tend to decrease lower esophageal pressure, including smoking, the use of drugs such as theophylline, and the presence of anatomic abnormalities.

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Adult Acute Non-Lymphocytic Leukemias: Current Concepts and Future Directions

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ABSTRACT—Despite higher complete remission rates of 50-80% in acute non-lymphocytic leukemia, it is discouraging that the majority of patients relapse within one year of achieving remission from their disease. Although median survivals in acute myelogenous leukemia are between one and two years, the 40% long-term disease-free survival seen in childhood acute lymphatic leukemia has not been achieved. Current investigational efforts are being directed at the development of new anti-leukemic drugs to hopefully prevent the emergence of drug-resistant leukemic clones, at the use of "late intensification" therapy to eradicate dormant leukemic cells and at improving supportive care measures for the infected pancytopenic patient through transfusion therapy and protected environments.

The adult acute non-lymphocytic leukemias (ANLL) are a group of diseases characterized by the malignant proliferation and accumulation of immature hematopoietic cells with subsequent bone marrow replacement and visceral organ infiltration leading to infection, bleeding, organ failure and eventually death. This review will summarize kinetic abnormalities of the acute leukemias, review a new international classification system, highlight the relationships of ANLL to other hematologic disorders, and discuss the current chemotherapeutic and immunotherapeutic strategies of treatment.

Cell Kinetics

At the time of diagnosis of human acute leukemia, the total body burden of leukemic cells has been estimated to be between 10^{11} to 10^{13} (average 10^{12}) cells. A three log reduction from 10^{12} (one trillion = 1 kilogram) to 10^{9} (one billion = 1 gram) cells results in a clinical remission. However, if one assumes that human leukemia is uniclonal in origin and that a single leukemic cell can reproduce to a lethal number, then to achieve cure of the disease it is necessary to eradicate all leukemic cells which have the potential to reproduce. Likewise, if the leukemic cell doubling time is 4-5 days, then 10 doublings would bring the number of leukemic cells from 10^{9} (remission) back to 10^{12} (relapse) in 40-50 days. Since the doubling time increases and the growth fraction (that fraction of the cell population actively proliferating and thus progressing through the cell cycle) decreases as the leukemic cell population expands, the reappearance of 10^{12} cells might take 2-4 months which seems to be the case in the unmaintained patient who achieves clinical remission.[1]

Although a prolonged course of antileukemic therapy may be "curative" in terms of eradicating all leukemic cells, it is necessary that a sufficient number of hematopoietic pluripotent stem cells survive. Current chemotherapy schedules all reflect the use of short intensive courses of drug treatment with rest periods to allow normal cells to recover. One hopes that normal cells will recover more rapidly than the leukemic cells so that with each course of antileukemic treatment a further relatively selective log kill of leukemic cells will result in the elimination of the last viable cell. The three main obstacles to achieving eradication of all leukemic cells in the patient are drug resistance, sanctuary sites of disease (leptomeninges, testes) and the small fraction of leukemic cells which stay in an extended dormant or resting phase (Go) and hence are unaffected by drugs.

The differences in clinical presentation of ANLL (fulminant disease vs. smouldering leukemia vs. preleukemic states) represent a complex interaction of several kinetic factors: the fraction of the leukemic

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population actively proliferating (growth fraction), the time required for each cell to pass from one mitosis to the next (generation time), the fraction of cells which have the capacity for unlimited reproduction (clonogenic fraction) and the fraction of cells which leaves the proliferating pool to mature or die (rate of spontaneous loss).

If one compares the durations of the phases of the cell cycle (G_1, S, G_2, M) of human acute leukemic myeloblasts to normal myeloblasts, one finds that the generation time of normal myeloblasts averages 40 hours compared to an average of 45 hours (range 25-360 hours) for leukemic myeloblasts. In other words, it takes *longer* for the leukemic blast to traverse the cell cycle than for the normal blast.[2 3] The variability of the G_1 portion of the cell cycle (16 hours in normal myeloblasts versus 10-200 + hours in leukemic myeloblasts) accounts for this surprising observation. Kinetic measurements suggest that the growth fraction of the leukemic cell population is smallest at the time of clinical diagnosis. As leukemic cells are destroyed by chemotherapy, cells in the resting phase (Go) of the cell cycle are capable of returning to active proliferation. Thus in "early" leukemia (10^9-10^{10} cells) as compared to "late" leukemia (10^{12} cells), the population doubling times have been estimated at 106 hours vs. 264 hours, labeling indices at 38% vs. 19%, and mitotic indices 2% vs. 0.9% respectively.[23]

General principles of antileukemic therapy should then include agents which exert their effects in different phases of the cell cycle. Agents which are maximally cytotoxic in the same phase of the cell cycle may not provide additive effects. In addition, the effectiveness of sequencing combinations may be influenced by using an agent which arrests (blocks) cells at one stage of the cycle followed by one which kills cells maximally at the point of the block itself or in the phase immediately succeeding the block.

Treatment programs in clinical practice often make use of an induction phase to reduce the number of leukemic cells from 10^{12} to 10^9 (clinical remission), a consolidation phase to provide further cytoreduction, a maintenance phase or late intensification phase to kill any remaining resting cells or slowly proliferating cells, and often central nervous system prophylaxis to kill any cells sequestered in the leptomeninges.

However, great difficulty still remains in defining the optimal sequence of antileukemic drugs as can be seen with cytosine arabinoside and the anthracycline antibiotics, daunorubicin (daunomycin) and doxorubicin (Adriamycin). There are no differences in complete remission rates when the two most active antileukemic drugs, cytosine arabinoside and an anthracycline are given sequentially or simultaneously.[3] Anthracylines given first do not cause a consistant increase in the growth fraction of leukemic cells to make them ready for the killing effect of cytosine arabinoside in the S phase. In fact the number of cells in the S phase is often decreased. Likewise, cytosine arabinoside given first may cause an accumulation of cells in the S phase, but increased killing in the S phase by the anthracycline is not seen.

Classification of ANLL

The acute leukemias represent a heterogeneous group of diseases with different clinical presentations, responses to therapy and prognoses. Methods for characterizing blast cells have included morphology, cytochemistry, electron microscopy, immunology, biochemistry and cytogenetics. A French-American-British (FAB) classification system was proposed in 1976.[4] The FAB system was designed to allow workers to more accurately identify subgroups of leukemics in order to better relate treatment modalities to clinical features of disease and prognosis. The FAB classification defines six myelocytic variants, designated M1 through M6. The M1 through M3 variants show predominantly granulocytic differentiation. The FAB classification defines two variants which include a monocytic component, M4 and M5, and one variant with an erythrocytic component, M6. With a uniform program of intensive antileukemic therapy, no correlation between the FAB subclass of ANLL and response to therapy, remission duration or survival has been evident.[6]

Relationship of ANLL to Other Diseases

Current theories of the etiology of the acute leukemias have been reviewed in detail by Necheles[7] and will not be discussed here. The incidence of acute myelogenous leukemia in the United States is 2.2 cases per 100,000 people per year. Acute leukemia has been reported as a terminal event in a wide variety of hematologic disorders and in association with solid tumors, renal transplantation and connective tissue diseases.[9] Acute leukemia as a consequence of non-leukemic hematologic disorders has recently been summarized,[10] and is outlined in Table 1. In view of the potential for long-term disease-free survival and possible cure following treatment for Hodgkin's disease,[11] malignant lymphoma[12] and ovarian carcinoma,[13] the increased risk of the late development of acute leukemia is disturbing. A number of reviews from cooperative oncology groups and from large cancer centers indicate that there is an excessive risk for the development of acute myelogenous leukemia after treatment for Hodgkin's disease,[14-16] malignant lymphomas[17 18] and ovarian cancer.[19 20] The common features noted are a long latent period following the diagnosis and initial treatment of the primary malignancy (usually greater than 3 years), a prolonged exposure to alkylating agents and the use of radiation therapy (especially total nodal fields).[9] The literature suggests that combined modality therapy may be associated with the highest risk of the development of acute leukemia. It is difficult to define the denominator for patients at risk for

Table 1

ACUTE LEUKEMIA AS A TERMINAL EVENT IN NON-LEUKEMIC HEMATOPOIETIC DISORDERS[a]

1. Hereditary disorders
    a. Fanconi's anemia (constitutional aplastic anemia with characteristic physical anomalies)
    b. Ataxia telangiectasia
    c. Bloom's syndrome
    d. Kostmann's syndrome (infantile genetic agranulocytosis)
2. Acquired non-malignant hematopoietic disorders
    a. Idiopathic aplastic anemia
    b. Chemical or drug associated - benzene, chloramphenicol alkylating agents
    c. Ionizing radiation
    d. Paroxysmal nocturnal hemoglobinuria
    e. Idiopathic sideroblastic anemia
    f. Polycythemia rubra vera
3. Acquired malignant hematopoietic disorders
    a. Multiple myeloma
    b. Hodgkin's disease
    c. Malignant non-Hodgkin's lymphomas

[a] modified from reference 10.

developing acute leukemic at the present time. It has been argued that acute leukemia may be a "natural" outcome for some long-term survivors of otherwise fatal neoplasms, especially those of a hematologic nature. However, the associations of ionizing radiation and leukemia in the Japanese during World War II[21] and immunosuppressive agents and leukemia in non-neoplastic disorders[22-24] makes this hypothesis unlikely as the sole explanation for the increased risk of leukemia following treatment for lymphoma and ovarian cancer.

Myelodysplastic Syndromes

Idiopathic myelodysplastic syndromes are a group of disorders having in common defective red cell production unresponsive to specific treatment, often in association with disordered granulopoiesis and thrombopoiesis. These conditions may presage the development of acute myelocytic leukemia.

Refractory anemia with an excess of blasts (RAEB) is the most frequent of the idiopathic myelodysplastic syndromes and has often been called preleukemia or smouldering leukemia. These terms imply that all patients will eventually develop leukemia yet only about 30% do, even with long term follow-up. Hence the term preleukemia should be used only in retrospective fashion. Differentiation between RAEB and acute myelocytic leukemia may require repeated bone marrow examinations in order to assess the stability of the blast and promyelocytic cell populations. Myeloblastic proliferation is often but not invariably present within a short time.

Myelodysplastic syndromes appear to represent a spectrum of disorders that often present with unexplained cytopenic states and progress through RAEB, smouldering leukemia and acute leukemia. Early clues to diagnosis in the peripheral blood may include variable degrees of anemia, neutropenia, thrombocytopenia, monocytosis, oval macrocytosis, nucleated red cells, hyposegmented granulocytes (Pelger-Huet like), and bizarre platelets. Bone marrow examination is always hypercellular and may reveal sideroblasts, megaloblastoid erythropoiesis, abnormal and/or increased megakaryocytes, a left shift in the myeloid series, and the absence of overt leukemia (including the absence of Auer rods).[25,26]

Antileukemic therapy is contraindicated in "preleukemic" states, RAEB, smouldering leukemia and chronic (subacute) myelomonocytic leukemia because patients often remain stable without treatment for many months or years. There is no information to demonstrate that early treatment modifies the natural outcome of this spectrum of disorders.[4]

Treatment

Current induction regimens for the treatment of adult ANLL employ both cytosine arabinoside and an anthracycline antibiotic (daunorubicin or doxorubicin) and are capable of achieving complete remission rates of 50-82%.[27,28] These results appear additive when compared to studies using each agent alone. Two studies suggest that the use of 6-thioguanine may add slightly to the complete remission rate.[29,30] Whether daunorubicin is superior to doxorubicin (Adriamycin) for remission induction is unclear at the present time. Adriamycin-containing regimens are capable of achieving complete remissions of 70-82% thus rivaling those regimens containing daunorubicin.[28,30,31] Cancer and Acute Leukemia Group B is currently in the process of prospectively comparing in a three arm study seven and three day courses of cytosine arabinoside and an anthracycline antibiotic respectively. Cytosine arabinoside is administered in a dosage of 100 mg/M^2 IV continuous infusion days 1-7 in all arms. The anthracycline antibiotics being compared are Adriamycin 30 mg/M^2 IV push days 1-3, daunorubicin 30 mg/M^2 IV push days 1-3 and daunorubicin 45 mg/M^2 IV push days 1-3. Preliminary results show no obvious differences in complete remission rates but toxicity data illustrate the need to reduce the dosage of anthracycline in patients with impaired hepatic function.[32,33]

The relative roles of consolidation and maintenance therapy in prolonging the length of initial remission and overall survival remain unclear. Median initial remission durations in various programs utilizing consolidation and/or maintenance therapy appear to be in the order of 5-13 months.[34-37] One study utilizing cytosine arabinoside, daunorubicin and 6-thioguanine induction therapy then compared in a randomized fashion cytosine arabinoside plus 6-thioguanine maintenance to no maintenance at all in the group of complete responders.

Although median remission duration was prolonged in the maintained group, overall survival results were not statistically significant between the two groups.[38] A novel approach has been taken at the M.D. Anderson Hospital in an attempt to prolong initial remission status. Following initial induction of complete remission and one year of maintenance therapy, patients still in continuous complete remission were treated with a combination chemotherapy regimen different from the one that had been used in initial remission induction, and then with bacillus Calmette Guerin (BCG) for an additional year.[39 40] Of 62 patients entered into the program of late intensification, 29 (47%) are still in complete remission, 12 of whom have been off chemotherapy for more than 4 years. Of major importance is the observation that 94% of the relapses occurred within the first 2 years of the completion of late intensification.

The immunotherapy of acute myelogenous leukemia is reviewed in detail by Murphy and Hersh[41] and by Alexander and Powles.[42] The results of trials incorporating BCG alone, allogeneic cells plus BCG, methanol extractable residue (MER) of BCG and allogeneic cells plus MER-BCG have yielded inconsistant results in terms of increasing overall survival, remission duration and survival after initial relapse when compared to chemotherapy alone. Differences in study design, lack of prospective randomized controls and small numbers of patients are major factors accounting for some of these differences. Despite initial complete remissions rates of greater than 60%, a major impediment to the improvement of survival of adults with ANLL is a lack of effective treatment after initial relapse. Of several newer chemotherapeutic agents, only 5-azacytidine has been shown to have significant antileukemic activity with complete remission rates of 20-30% in patients refractory to "standard" treatment.[43-46] Since remission durations with 5-azacytidine have been short, the role of 5-azacytidine as part of initial induction therapy needs to be explored. In a pilot study for initial remission induction therapy testing the efficacy of 5-azacytidine in consolidation therapy, a disappointing 53% complete remission rate was obtained when cytosine arabinoside and daunorubicin were combined in a 5 plus 3 day combination.[47]

Supportive Care

Red Cell Transfusions

Red cell replacement therapy is necessary for almost all acute leukemia patients to prevent the adverse consequences of anemia and hypoxemic organ damage. With the exception of massive gastrointestinal hemorrhage requiring whole blood, red cell replacement should be in the form of packed red cells made buffy coat poor, or in the form of frozen cells which are washed during the process of deglycerolization and thus separated from most of the leukocytes and almost all of the plasma components. Packed red cells minimize the hazard of volume overload in the patient with borderline cardiac reserve while removal of leukocytes minimizes febrile reactions to pyrogens and leukocyte antigens. The cost of frozen red cells is high but offers the advantage of infrequently being associated with urticarial, anaphylactic and leukoagglutinin reactions. Red cell transfusions have been associated with the transmission of infection (viral hepatitis, cytomegalovirus, toxoplasmosis, malaria), sudden intravascular hemolysis secondary to ABO incompatibility, delayed intravascular hemolysis due to Rh incompatibility and delayed intravascular hemolysis secondary to minor blood group incompatibility. Rarely post-transfusion purpura in P1A[1] negative recipients may occur.[46] Red cell transfusions should be given as needed to maintain the hemoglobin $>$8 gm/dl or whenever the patient is symptomatic at any hemoglobin level above 8 gm/dl.

Platelet transfusions

The availability of platelet transfusions has reduced the incidence of hemorrhagic death in leukemia from 70-80% to 20-30%. The risk of hemorrhage climbs markedly when platelet counts are below 20,000 cells/mm^3[49] although hemorrhagic phenomena may be evident at higher platelet counts in the presence of bacterial sepsis, gastrointestinal bleeding and disseminated intravascular coagulation. In general, platelets are transfused prophylactically when the platelet count is < 15,000 ± 5,000 cells/m^{3}or at any level if microscopic hematuria, positive stools for occult blood or fresh fundal hemorrhages are noted.[50]

Platelets lack Rh antigens but have A antigens. Platelet sources may include random donors, HLA matched donors (related or unrelated to the patient) and frozen autologous platelets obtained from the patient when in remission.[51] In general one unit (approximately 5 - 10 x 10^{10} platelets) of random donor platelets yields a 5000 - 10,000 cell/mm^3 increment with a half-life of 3-4 days when transfused into the non-sensitized recipient. About 30% of each platelet unit is immediately sequestered in the spleen. Sensitization due to iso and alloantibodies, bacterial sepsis, bleeding, and disseminated intravascular coagulation all tend to decrease the expected platelet increment. Usually 6 to 10 platelet units are transfused from a random donor source. HLA compatible donors are used when alloimmunization to platelet antigens results in refractoriness to platelet transfusions.[51] Interestingly, prior random donor platelets does not prejudice the subsequent utility of HLA-matched platelets.

Granulocyte transfusions

Infection remains the leading cause of death in acute leukemia and becomes a major threat to survival with absolute neutrophil counts < 1000 cells/mm^3.[52] Large numbers of granulocytes estimated to be in the order of 5 x 10^{10} cells are need to raise the granulocyte count from 0 to 2000 cells/mm^3. If the total blood volume of an adult contains 1-2 x 10^{10} granulocytes, then approximately 30-40 units of blood would be needed to yield this increment. Further complicating matters is the short 4-7 hour half-life of granulocytes in the peripheral circulation.

Three methods are available for procuring granulocytes: continuous flow centrifugation (CFC), intermittent flow centrifugation (IFC) and filtration leukapheresis (FL).[50] The first two methods permit an average four hour collection from the donor of 1-1.5 x 10^{10} mature functionally intact granulocytes. FL permits the collection of 5-10 x 10^{10} granulocytes but the procurement method often results in degranulation of the granulocytes together with the production of superoxide radicals leading to functional abnormalities in in vitro tests and possibly in vivo.[51] However, granulocytes collected by all methods may have clinical utility.

The therapeutic role for neutrophil transfusions remains unclear. Although it appears that survival of neutropenic septic patients given granulocyte transfusions and antibiotics is better than that of neutropenic septic patients given antibiotics alone, the benefit of granulocyte transfusions has only been seen in patients whose granulocyte counts did not recover spontaneously within 1-2 weeks from the beginning of a septic episode. Those whose counts recovered normally did just as well with antibiotics alone.[51] Granulocyte transfusions seem to provide a short term increment in survival by preventing septic deaths during severe marrow hypoplasia. This is only translated into long term survival if the bone marrow recovers and control is gained over the neoplastic process by intensive chemotherapy. Criticisms that have been directed at the controlled studies reported[53] have emphasized that small numbers of patients have been studied, usually less than 20 per control group or transfused group, that within each group there is a heterogeneity of underlying diseases, that different antibiotic practices are evident even within a single study and that a delay of 48-72 hours in beginning granulocyte transfusions preselects a subset of patients potentially resistant to antibiotics. The importance of starting neutrophil transfusions at the time of initial sepsis versus a 2-3 day delay is unknown. Likewise, patients with fever and negative cultures have not been shown to benefit from granulocytes.[54]

Protected Environments

Although antibiotic treatment has improved over the past decade, the fatality rate from infection in the acute leukemia patient remains high especially if the patient fails to rapidly achieve a complete remission. Total protected environments have been developed to attempt to minimize septic death in the neutropenic, immunocompromised host. Provisions that have been thought necessary include patient isolation, air filtration, gastrointestinal and cutaneous decontamination, and "sterile" food and water supplies. While protected environments have theoretic benefits, they are extremely expensive to operate from both financial and manpower aspects. Their routine use for high risk patients should thus be founded on information proving enhanced survival without long-term psychological and physical sequelae.

The available data from six randomized clinical trials demonstrates the ability of protected environments (laminar air flow rooms plus prophylactic oral non-absorbable antibiotics) to decrease the incidence of infectious complications during intensive chemotherapy of acute leukemia as compared to control groups of leukemic patients.[57] However, episodes of severe infection have not been totally eliminated because of persistent and resistant organisms. Thus the total protected environment is not totally protective. In attempting to define the relative contributions of filtered air systems, protected environments without prophylactic antibiotics, and prophylactic antibiotics alone, firm conclusions cannot be reached due to small numbers of patients in a number of trials, the use of historical controls and variations in antibiotic regimens.[57] Isolation alone may be of value without prophylactic antibiotics but only one controlled study suggests this.[58]

Twelve clinical trials attempt to answer the question as to whether protected environments and/or prophylactic antibiotics enhance remission rates and remission duration in leukemia. Results are contradictory due to imbalances in the characteristics of control and special treatment groups, small number of patients in many of the trials and variations in remission induction chemotherapy within individual trials.[57] Of interest is the recently reported M.D. Anderson Hospital trial[59] demonstrating a significant decrease in *fatal* infections in patients treated within the protected environment (including prophylactic antibiotics) but not in overall major infections. (fatal and non-fatal). In addition, patients within the protected environment had a significantly longer duration of survival from diagnosis but surprisingly did not have a significantly longer initial remission duration. The reason for this is unclear. The major criticism of this study is the high early death rate in the group of patients not assigned to the protected environment before an adequate trial of chemotherapy could be given. This suggests that the control and protected environment groups of patients may have been "biologically" unbalanced.

Bone Marrow Transplantation

Bone marrow transplantation has been pioneered by the Seattle group for the treatment of patients with acute leukemia.[55] A recent update revealed 3 of 14 long-term (52-67 + months) identical twin transplant survivors and 6 of 58 long-term (21-63 + months) allogeneic transplant survivors among patients treated with marrow transplants for acute myelogenous leukemia.[56] Despite the encouraging results, recurrent leukemia during the first two years post-transplantation and infection remain major problems for both syngeneic and allogeneic transplants. Graft versus host disease with its attendent problems of skin, hepatic and gastrointestinal organ dysfunction and failure poses a major threat for the allogeneic marrow recipient despite major histocompatibility locus matching.[56] At present bone marrow transplants are being performed in ANLL patients in complete remission with the hope of providing for long-term disease free survival. The rationale underlying this experimental approach takes into account the fact that the remission duration of ANLL is short, the chances for a second durable remission are small, the leukemic cell burden is "minimal" when a complete remission is obtained and the patient may be in optimal medical condition when in first remission. For the patient with an identical twin donor and acute myelogenous leukemia, bone marrow transplantation may be the treatment of choice.

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Undifferentiated Carcinoma in Young Men

Patients with a histologic diagnosis of metastatic undifferentiated carcinoma with an unkown or undetected primary site are commonly referred to oncology units. Fox and his associates describe their experience with five young men who had extensive malignant disease involving the lung, mediastinum and lymph nodes, and a referred histologic diagnosis of undifferentiated carcinoma.

Careful study revealed extragonadal germ cell tumors to be the cause of the presenting manifestations. None of the patients had clinical evidence of primary testicular tumors. Response to treatment, tumor marker analysis (serum human chorionic gonadotropin and alpha-feto-protein) and histologic review suggested the diagnosis of extragonadal germ cell tumor.

In previously reported cases, the majority of patients with extragonadal germ cell tumors have had obvious anterior mediastinal masses as the predominant feature of their disease. However, the authors now consider nontesticular germ cell tumor as a possible diagnosis in young men presenting with undifferentiated carcinoma without an obvious primary site.

Experience with the current therapeutic regimen (cis-platinum, vinblastine and bleomycin) for nontesticular germ cell tumor is limited, but it appears that some response can be expected. Thus, it is important to establish a diagnosis of germ cell tumor in young men presenting with metastatic undifferentiated carcinoma.

—*Lancet,* June 23, 1979, p. 1316

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Brief Summary

INDICATION: Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described below

CONTRAINDICATIONS: Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma Agitated states Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors, (hypertensive crises may result).

WARNINGS: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly *Drug Dependence* Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia *Use in Pregnancy:* Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children*: Tenuate is not recommended for use in children under 12 years of age.

PRECAUTIONS: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

ADVERSE REACTIONS: *Cardiovascular*: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System*: Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal*: Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic* Urticaria, rash, ecchymosis, erythema, *Endocrine*: impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System*. Bone marrow depression, agranulocytosis, leukopenia *Miscellaneous* A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.

DOSAGE AND ADMINISTRATION Tenuate (diethylpropion hydrochloride) One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release One 75 mg tablet daily, swallowed whole, in midmorning. Tenuate is not recommended for use in children under 12 years of age.

OVERDOSAGE: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard Intravenous phentolamine (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of April, 1976

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Guidelines for the Management of Patients Hospitalized with Viral Hepatitis

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE, CENTER FOR DISEASE CONTROL

For many years the Center for Disease Control[1] and the American Hospital Association[2] have recommended that patients admitted to the hospital with a diagnosis of viral hepatitis B be placed in 2 categories of isolation—Enteric Precautions and Blood Precautions.

This disease-control strategy is based on 1) the inability until recently to differentiate clearly between the etiologic forms of the disease and 2) the assumption that feces and blood from patients with either hepatitis A or hepatitis B might be infective. It is now known that transmission routes for type A and type B are different when viewed in the context of communicability of disease. For example, patients infected with hepatitis A virus (HAV) do not have a viremic stage that is extensive enough to pose a problem of disease transmission through direct contact with blood. In contrast, the blood of patients with acute hepatitis B is often infective, but the virus is not trasmitted via the enteric tract.

Although the enteric route is the principal mode of transmission for hepatitis A, recent epidemiologic and laboratory studies have shown that maximal levels of HAV excretion occur before the onset of jaundice. Consequently, when symptoms develop in an HAV-infected person and the person is hospitalized, the patient usually is excreting only low levels of HAV in stool. Hepatitis A has not been a significant nosocomial problem in the United States. Although it is possible for hepatitis A to be transmitted in a hospital, the probability that this will happen appears to be low. In the few instances where such transmission has been reported, unusual circumstances have surrounded the event. Nonetheless it is evident that precautions must be taken when staff members are directly in contact with the patient's feces. The question arises as to the degree of enteric precautions necessary. Currently, some hospitals practice what might be considered extraordinary enteric precautions in which patients are isolated in private rooms, all staff members gown and glove when entering the room, and the patients have separate toilet facilities. We believe that this degree of isolation and precaution is not justified. Rather, one can use the same precautions that are used for handling feces from all other hospitalized patients, which should include wearing gloves when handling bedpans or fecal material or when using instruments that come in contact with the intestinal tract. A private room is not needed unless a patient is fecally incontinent.

Although it has been common practice to place patients who are known to have hepatitis B infection under enteric precautions as well as blood precautions, there is general agreement that a fecal-oral route of transmission of hepatitis B virus does not exist. Many body fluids, secretions, and excretions—including urine, feces, saliva, nasopharyngeal washings, breast milk, bile, semen, synovial fluids, sweat, tears, and cerebrospinal fluid—have been hypothesized as being infective because they contain detectable hepatitis B surface antigen (HBsAg). Although saliva and semen have been shown to be infective, blood is the most consistently efficient vehicle for transmitting hepatitis B virus. Hepatitis B is a major nosocomial problem among patients and staff members, and consequently there is no question that blood precautions should be employed constantly. However, since fecal-oral transmission does not occur, the placing of patients admitted

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with a diagnosis of hepatitis B under enteric precautions is not warranted.

When a patient is admitted to a hospital with a diagnosis of hepatitis, but it has not been determined whether the type of disease A, B, or non-A, non-B (hepatitis B and non-A, non-B hepatitis are epidemiologically similar), the primary precaution category should be blood precautions, and the patient should be cared for in the same fashion as described for hepatitis B. Certainly, as with all other patients, caution should be used when handling feces or soiled objects or when handling instruments contaminated with feces.

Hepatitis Precautions—Specific Recommendations

General—The care of patients hospitalized with a diagnosis of viral hepatits A or B, non-A, non-B hepatitis, or hepatitis of unspecified type should emphasize blood precautions. The same precautions that should be used when handling feces, urine, and excretions from all other hospitalized patients should be used for patients admitted with a diagnosis of viral hepatitis. These guidelines pertain to all patients hospitalized with a diagnosis of viral hepatitis B regardless of hepatitis B e antigen (HBeAg) status and including those who are in hematology-oncology units. However, for HBsAg-positive patients who are being treated by chronic hemodialysis there are several additional precautionary and preventive measures that should be employed. These specialized control measures are beyond the scope of this report, and readers are referred to the publication "Center for Disease Control: Hepatitis—Control Measures for Hepatitis B in Dialysis Centers. Viral Hepatitis Investigations and Control Series, November 1977." This report is available from the Hepatitis Laboratories Division, Center for Disease Control, 4402 North Seventh St., Phoenix, Arizona 85014.

Private room—The patient need not stay in a private room unless he or she is fecally incontinent, as with small children, and the type of hepatitis is unknown or has been shown to be non-B hepatitis. Because the continence of young children is especially difficult to ensure and because their toys and books can become soiled with feces, consideration should be given to isolating all young children with viral hepatitis in a private room.

Gloves—Persons must wear gloves when having direct contact with the patient's feces, blood, or articles contaminated with blood or feces or when using instruments for vascular access. Persons who have dermatitis should wear gloves for all patient contact.

Hands—Hands must be washed before and after direct contact with the patient or with items in contact with the patient's blood or feces.

Gowns—Persons should wear gowns when having contact with the patient's blood or feces, carrying out procedures in which excessive blood spills or spatters may occur, or using instruments on a patient in such a manner that excessive fecal or blood contamination can be expected, i.e., proctoscopy.

Masks—Masks are not necessary for normal patient contact including venipuncture. However, if the patient is being treated or is undergoing instrumentation in such a manner that blood or feces may be spattered, masks should be worn.

Articles, such as books, magazines, and toys—These items require no special precautions unless they are contaminated with visible feces or blood. Infected children should not share toys. Contaminated articles should be wiped clean with a detergent and wiped with a disinfectant.

Sphygmomanometer and stethoscope—These items require no special precautions unless contaminated with visible feces, blood, or other body fluids containing blood. If contaminated, the articles should be cleaned with a detergent solution and wiped with a disinfectant.

Thermometers—The thermometer, its container, and a suitable disinfectant such as 0.2% iodine in 70%-90% alcohol should remain in the patient's room, and the disinfectant should be changed every 3 days. Oral thermometers may be kept dry; before and after each use, they should be washed with soap and water, rinsed, and wiped dry.

Needles and syringes—Special precautions should be taken when blood is collected from patients with hepatitis. Disposable needles and syringes should be used. They must not be reused. Used needles should not be recapped; they should be placed in a prominently labeled, impervious, puncture-resistant container designated for this purpose. Needles should not be intentionally bent or broken by hand, since accidental needle puncture may occur. Used syringes should be placed in an impervious bag. Both of these containers should be incinerated or autoclaved before discarding. Reusable syringes should be rinsed thoroughly in cold water by a person wearing gloves, then wrapped by using the double-bag technique, with the outer bag labeled "HEPATITIS." The syringes should remain bagged until they have been decontaminated or sterilized.

Dressings and tissues—These items should be placed in an impervious plastic or paper bag, closed securely. The bag should be discarded in the room in a wastebasket lined with an impervious plastic bag. On removal, the wastebasket liner should be sealed and then disposed of properly. Local regulations may call for incineration or disposal in an authorized sanitary landfill without being opened. Impervious bags should be readily available at the patient's bedside.

Urine and feces—The usual precautions practiced when handling urine and feces of all other hospitalized patients should be employed when handling urine and feces of hepatitis patients. For example, when directly handling urine and feces or their containers, personnel should wear gloves, and urine and feces should be flushed directly down the toilet. Utensils should be cleaned and replaced at bedside. Each patient should be assigned a bedpan, and after the patient is discharged from the hospital, the bedpan should be cleaned and disinfected or sterilized. Unless they have fecal incontinence or behavioral problems, patients with hepatitis may share a toilet facility with other patients. Each patient must wash his or her hands after using toilet facilities.

Special instruments (endoscopes, cystoscopes, proctoscopes, colonoscopes, bronchoscopes, nebulizers, IPPB machines, etc.)—No special precautions are required for specialized instruments except those used for vascular access or ones which may be contaminated with blood or feces. After use, instruments should be cleaned thoroughly and sterilized or disinfected with an appropriate high-level disinfectant.

Linen—No special precautions are needed with linens unless they are contaminated with visible feces or blood, in which case they should be put in a laundry bag in the patient's room. A hot-water-soluble bag is preferable. The water-soluble bags containing contaminated linen should be placed unopened in hospital washing machines. Bags that are insoluble must be opened and the contents carefully dumped into washing machines without being sorted; the bags must also be washed or discarded. For incontinent patients, mattresses and pillows should be covered with impervious plastic. This covering should be cleaned with a germicidal detergent solution or removed with the linens and laundered at the time of terminal disinfection.

Dishes—No special precautions are needed.

Drinking water—No special precautions are needed.

Clothing and personal effects—No special precautions are required for these items unless there is visible contamination with feces or blood, in which case clothing should be treated as linen and personal effects as articles.

Laboratory specimens—Specimens (urine, sputum, feces, and blood) should be put in sterile, labeled containers with the lids securely closed. Containers should be prominently labeled "HEPATITIS" so that ward transport and laboratory personnel can take necessary precautions while handling and processing them.

Patient's chart—No special precautions are required.

Visitors—No special precautions are required.

Transporting patients—No special precautions are required except that clean sheets and pajamas should be used for fecally incontinent patients.

Concurrent cleaning—Routine daily cleaning procedures that are used in the rest of the hospital ward can be used for rooms housing hepatitis patients. Special attention should be given to areas or items grossly contaminated with feces or blood. Cleaning personnel must be alerted to the potential hazards associated with feces, blood, and serum contamination from hepatitis patients. Floors and other environmental surfaces contaminated with visible blood or feces should be thoroughly cleaned with a detergent disinfectant. Gloves should be worn by cleaning personnel performing these duties.

Terminal disinfection—No special precautions are required for terminal disinfection except as described under "Concurrent cleaning."

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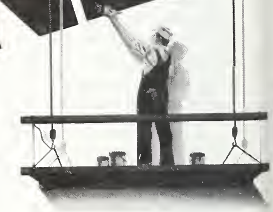

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The Food and Drug Administration's Drug Approval Process

GREGORY J. AHART

Mr. Chairmen and Members of the Subcommittee, we are pleased to be here today to discuss the results to date of our review of the Food and Drug Administration's (FDA's) process for approving new medical drugs for marketing in the United States.

Our review, as you know, was undertaken in response to a request from the Chairman of the Subcommittee on Domestic and International Scientific Planning, Analysis, and Cooperation which in the current Congress was merged with the Science, Research and Technology Subcommittee. Our review was directed at determining (1) whether there are inordinate delays in processing and approving new drugs for marketing in the United States; (2) whether delays in approving new drugs adversely impact on the introduction into the United States of therapeutically important drugs that are available in other countries; (3) how FDA's drug approval process compares with approval processes of other technologically developed countries; and (4) whether innovative use of computer technology could eliminate inordinate delays in the drug approval process.

General Background

The Federal Food, Drug, and Cosmetic Act and implementing regulations for investigational use of new drugs require FDA to exercise close control over the clinical, or human, testing of new drugs. The act requires that, before a new drug may be introduced into interestate commerce, FDA must approve the drug for safety and efficacy.

A new drug is defined by the act as any drug not generally recognized, among qualified experts, as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling. A new drug may be an entirely new substance or a marketed drug in a new formulation or for a new use, that is, a use for which the drug is not approved.

To satisfy FDA requirements for safety and efficacy, a sponsor of a new drug must clinically test the drug under closely controlled circumstances. A sponsor is the person who assumes responsibility for an investigation of a new drug. Sponsors generally fall into three categories: drug manufacturers, private and Government agencies, or individual physicians. The evidence of safety and efficacy obtained from clinical studies is included in a new drug application, (NDA), submitted to FDA by a sponsor who usually is a drug manufacturer seeking to market a new drug product.

The NDA contains: (1) full reports of investigations, including animal and clinical investigations, which have been made to show whether or not the drug is safe and effective; (2) a statement of the drug's composition; (3) a description of the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the drug; (4) samples of the drug and components as may be required; and (5) copy of proposed labeling.

To review the data submitted, FDA uses a team of three primary reviewers including a medical officer who reviews the clinical test results, a pharmacologist who reviews the animal test results, and a chemist who reviews the chemistry and manufacturing controls and process. The review teams may also be supported by a microbiologist and a statistician if appropriate.

The law provides that within 180 days after an NDA is filed, FDA must approve it or give the applicant notice of an opportunity for a hearing on the deficiencies found in the application. FDA may take longer than 180 days to decide on an application

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if the applicant and FDA agree to an additional period of time.

Important Drugs Take a Long Time to Approve

We noted that processing NDAs takes a long time. The statutory 180-day review time is generally not met. Our analysis shows that the average approval time for original NDAs submitted in calendar year 1975 was about 20 months. FDA's own analysis shows that the average approval time for 80 NDAs approved in fiscal year 1978 was about 34 months. These two analyses differ with respect to the number of NDAs involved. Our analysis included only NDAs submitted in 1975 and FDA considered all NDAs approved in 1978 some of which were submitted over a period of several years prior ot 1978.

NDAs that were involved in the lengthy review process included drugs FDA classified as being therapeutically important, and some of these were available in other countries before they were available in the United States. FDA considers a new drug important if it provides a major or modest therapeutic gain over any marketed drugs. Lengthy approval times for important drugs deprive the general public of the therapeutic advantages of such new drugs and, according to industry officials, adds substantially to the cost of developing the drugs.

A number of drugs submitted to FDA for approval in 1975 and classified by FDA as important took from 12 to 32 months to be approved; half took over 20 months. For example, dobutamine hydrochloride, a drug used for treatment of cardiac decompensation, a form of heart failure, was approved in July 1978, 31 months after it was initially submitted for approval. Another drug FDA classified as important is somatotropin. This drug, which is used to promote growth in children with short stature due to a deficiency of pituitary growth hormone, was approved on July 30, 1976, about 15 months after an NDA was submitted to FDA.

Both of these drugs were available sooner in other countries. Dobutamine was approved for use in the United Kingdom in September 1977. Somatotropin was approved for use in Sweden in 1971 and in the United Kingdom and Switzerland in 1972.

During the period July 1975 through February 1978 FDA approved 14 drugs it classified as important, including somatotropin. Thirteen of these drugs were available elsewhere 2 months to 12 years earlier than they were available in the United States. For example, an NDA for beclomethasone dipropionate, a drug used for the treatment of chronic asthma, was submitted to FDA in February 1974 and approved in May 1976 or 27 months later. This drug was available earlier in Norway, Sweden, Switzerland and the United Kingdom, and was approved in a much shorter period of time in all four countries. The approval times ranged from 4 months in the United Kingdom to 18 months in Sweden.

Other important drugs that were approved for use in other countries before they were approved for use in the United States include:

—Bromocryptine which was approved almost 3 years earlier in Switzerland. It is used to treat an endocrine disorder of the uterus and breast, Parkinson's disease and acromegaly.

—Dysopyramide which was approved more than 5 years earlier in the United Kingdom. It is used to treat abnormal heart rhythm.

—Propranolol which was approved more than 7 years earlier in the United Kingdom. This drug at the time of its introduction, represented a most important advance in treatment of high blood pressure.

—Sodium valproate which was approved about 11 years earlier in France. It is used to treat epilepsy.

In some of these cases an NDA was submitted to FDA before it was submitted to another country; but the drug was approved for maketing in the United States later. For example, an application for prazosin hydrochloride used to treat hypertension, was submitted for approval in the United States in February 1973 and in the United Kingdom in April 1973. This drug was approved for use in the United States in June 1976 or 40 months after the NDA was submitted, and in the United Kingdom in October 1973 or 6 months after application was submitted. An application for another drug, cimetidine, used to treat duodenal ulcers was submitted to FDA in July 1976 and 2 months later the application was submitted to the United Kingdom. This drug was approved by the United Kingdom in November 1976 and by FDA in August 1977

Physicians in other countries advised us of several important drugs licensed for use in those countries, which we found have not been approved for use in the United States. Among these are:

—Alprenolol, a drug which was approved in Sweden more than 3 years ago for prevention of death after heart attacks.

—Ancrod, a drug which has been marketed since 1974 in the United Kingdom and used as an anticoagulant to prevent or treat blood clots.

—Chenodeoxycholic acid, a drug which was approved in 1976 in Switzerland and is used to dissolve gall stones.

—Cyproterone, a drug which was approved 6 years ago in Germany and used in the treatment of sexual hyperactivity and precocious puberty.

Most of these drugs have been approved in the United States for clinical investigations.

According to officials in foreign drug regulatory agencies we visited, average approval times in some countries take longer than in the United States. These countries include Norway where the approval times range from 1 to 3 years, and Sweden where approvals averaged 27 months. However, in other countries the average approval time was from 7 to 12 months less than the 20 month average in the United States.

Because we did not have access to drug records of the foreign countries we were not able to determine why they approved drugs faster. However, there are a number of differences between the FDA and foreign drug approval processes.

But before I discuss these differences, I would like to talk about some of the factors that contribute to the slowness in the FDA drug approval process.

Factors Contributing to Slowness in Drug Approval Process

To determine why many NDAs took so long to process, we interviewed industry and FDA officials including FDA reviewers, and analyzed the processing of the 132 original NDAs submitted to FDA for approval in calender year 1975. In addition, we analyzed the workload of FDA reviewers.

According to industry officials the NDA approval process is hindered because:

- —FDA guidelines are not precise and therefore are subject to varying interpretations.
- —FDA changes reviewers during the NDA review which slows the process.
- —Scientific and professional disagreements between FDA and industry are not readily resolved.
- —FDA communications to industry are slow and there are long periods of time after submission of the NDA before the company is notified of any deficiencies.

On the basis of our analysis, industry appears also to have contributed to the slowness in processing NDAs by submitting incomplete NDAs and not giving high priority to correcting the deficiencies identified by FDA. Also, based on our analysis of FDA's workload, we found that it was unevenly distributed among reviewers which seems to further adversely impact on the approval timeframes.

Need clearer guidelines

According to industry officials, FDA guidelines are vague regarding the documentation to be submitted with an NDA. As a result, industry officials believe FDA reviewers use personal preferences and standards that differ among reviewers. One industry official described the situation as "the target moving faster than the bullet."

Our analysis of NDAs submitted for FDA approval showed that NDAs are often returned to manufacturers for additional information. For example, 100, or 76 percent of the 132 NDAs submitted to FDA for approval in 1975, were returned to manufactures one or more times for additional data. Most deficiencies related to chemistry and manufacturing control. In some cases, the correspondence between FDA and industry on such matters continued over a period of a year or more. Inasmuch as most NDAs failed to meet FDA requirements, it would appear that more specific guidance on the preparation and submission of NDAs would be helpful to manufacturers and would tend to speed up the process.

We contacted industry officials on 20 NDAs that had not been approved. Some of these officials cited FDA reviewers' inconsistency with regard to the amount of detail required with an NDA as a primary reason for deficiencies in the applications.

One industry official said that FDA reviewers require more detail today on chemistry and manufacturing controls than they did previously although the guidelines for the submission of such information have not changed since 1971.

FDA has recognized the need for improved guidelines and has stated that it plans to issue some of them later this year.

NDA reviewers change

In our discussions with drug industry officials, several pointed out that reviewers changed before the NDA processing was completed. This according to these officials has impacted on the time it has taken to review NDAs because the subsequent reviewer examined all the data that already had been reviewed, and raised additional questions on the data. Our analysis of 45 of the 132 NDAs showed that reviewers changed during the NDA processing in 17 cases. Futhermore, in 5 of the 17 cases the reviewers changed more than once.

We discussed reviewer changes with FDA officials. They explained that, generally, reviewers change when a reviewer leaves the agency or when the reviewer's workload necessitates a change to enable a more prompt review of pending NDAs.

Although some reviewer changes may be unavoidable, FDA should try to minimize such changes to reduce delays in approving NDAs.

Resolving scientific and professional disagreements

Industry officials told us that in some cases the issues raised by FDA involved areas of scientific disagreement. They said there was no formal mechanism for prompt resolution of these disagreements. Presently, manufacturers can request administrative hearings to resolve such issues. This procedure is time consuming and is used infrequently. Industry officials did not provide specific examples of NDAs where such disagreements delayed the approval process and we were unable to clearly identify such examples because of the technical nature of the issues discussed in correspondence between FDA and industry.

With regard to scientific disagreements, pending bills (S.1045 and S. 1075), which are cited as the Drug Regulation Reform Act of 1979, provide for informal and expeditious procedures for review and, if possible, resolution of scientific disagreements. Such legislation, we believe, would provide a useful mechanism for more promptly dealing with scientific disagreements.

Communications between FDA and industry need improvement

Officials from the companies we talked with said slow or inadequate communications from FDA contributed to delays in reviewing and approving NDAs. In fact, 3 of the 8 companies considered communication problems as the primary reason for delays. Some officials indicated that reviewers did not provide manufacturers with timely feedback on deficiencies noted in their reviews.

FDA reviewers corroborated industry's perceptions. Twenty-one, or 46 percent, of the 46 reviewers we interviewed said they did not notify manufacturers of NDA deficiencies until other members of the review team had completed their reviews. Medical officers, chemists and pharmacologists were consistent in this regard as 43 percent, 46 percent and 55 percent, respectively, said they did not notify drug companies until the other two reviewers finished their review.

We could not determine from FDA records we reviewed when the reviewers first notified the manufacturers of deficiencies in their NDAs. However we noted instances where some reviewers completed their work 1 to 4 months earlier than other reviewers of the same NDA. In an attempt to reduce the review time for important drugs, FDA now requires each of its reviewers to reply to the manufacturer when their reviews are completed rather than waiting until all team members have completed their reviews.

Industry Contributes to Delays

We followed up with industry on 20 NDAs not approved as of June 30, 1978, some 30 months or more after the applications were initially submitted. Generally, they agreed with FDA's findings on these NDAs. However, the manufacturers generally placed a low priority on resolving these deficiencies because they determined that these drugs had a limited market.

Another reason, according to FDA officials, for NDAs taking a long time to process is because industry sometimes submits incomplete NDAs. Three of the 20 NDAs we followed up on were incomplete according to FDA. These NDAs were for radiopharmaceutical drugs which were formerly regulated by the Atomic Energy Commission. This responsibility was transferred to FDA. Two of the radiopharmaceutical companies that sponsored these drugs told us the NDAs were incomplete because they had limited experience with FDA at the time they submitted the NDAs.

Uneven Distribution of Workload

Our analysis of FDA reviewers' workloads showed the workload varied widely, and this adversely impacted on the NDA review process. According to FDA officials, NDA review time could be shortened if workload could be more evenly shared by reviewers.

To gain insights on how workload is distributed within FDA, we analyzed the 1977 workload for 136, or 83 percent, of the 164 FDA drug reviewers. We concentrated our analysis on original NDA reviews because FDA officials cited them as the most complex and time consuming task for reviewers.

About 50 percent of the reviewers, which included medical officers, chemists, and pharmacologists, were responsible for reviewing most of the NDAs. Specifically, (1) fifty-one percent of the medical officers were assigned 88 percent of the NDAs; (2) forty-eight percent of the chemists were assigned 76 percent; (3) forty-nine percent of the pharmacologists were assigned 83 percent. This imbalance existed in most divisions. For example, 4 of the 8 medical officers in one division were assigned 20, or 87 percent, of the 23 NDAs in that division. In another division, 4 of the 8 chemists were assigned 28, or 82 percent, of the 34 NDAs. In a third division, 3 of the 6 pharmacologists were responsible for 53, or 88 percent, of the 60 NDA.

In many cases, reviewers with heavy NDA workloads also carried a large load in other drug review work. For example, one of 8 reviewers in one division with 22 percent of the original NDA workload was also responsible for 25 percent of the supplemental NDAs and 16 percent of the applications for investigational new drugs in his division group.

In January and February 1979, we discussed our workload analysis with FDA division directors. They said workload imbalances exist because:

—some reviewers are more proficient than others and therefore are assigned a heavier workload, and

—some reviewers with a heavy workload were supervisors who were reluctant to delegate work to others.

Review proficiency seems to be a function of individual capabilities and experience. Division directors said some reviewers were chronic low producers and, for practicial reasons, are assigned fewer NDAs. In addition, less experienced reviewers are assigned fewer and less complex NDAs for review. To help the workload problem, division directors told us they are conducting on-the-job training for less experienced reviewers and are counseling low producers to improve their performance.

We believe that effective on-the-job training and counseling for reviewers should permit FDA to distribute the workload more evenly. These measures, if effectively carried out, should help to improve FDA's drug review and approval process.

Comparison of United States Drug Approval System with other Countries' Systems

To obtain data on foreign drug approval systems, we visited nine countries and obtained the views of foreign regulatory and industry officials, medical experts, academicians and members of medical associations concerning the similarities and differences between their drug approval processes and those of the United States.

Some of the major differences relate to (1) use of expert committees, (2) post-marketing surveillance, (3) use of foreign test data to support safety and effectiveness of a drug, (4) flexibility in restricting the use of drugs, and (5) review of marketed drugs.

Expert Committees

FDA has a number of advisory committees not established by law who meet at irregular intervals and serve strictly in an advisory capacity. In contrast, most of the European countries we visited have established a committee of experts. In three of these countries Netherlands, Norway, and Sweden the committee had been given the responsibility to make the decision to approve, reject or withdraw a drug. In the United Kingdom, its committee advises the government agency on the safety and efficacy of a drug; however, we were advised that its recommendations have always been followed.

The proposed Drug Regulation Reform Act of 1979 calls for the creation of advisory committees. Although this would legislatively mandate the existence of such committees in the drug approval process, their advisory capacity would remain unchanged.

The advantages we see to using expert committees as in European countries are that decisions are made by recognized experts in their fields whose decisions are more likely to receive wide acceptance. The use of expert committees would also appear to serve as a buffer to civil servants from outside influence and criticism.

Post-marketing surveillance

The objective of post-marketing surveillance is to monitor the use of a marketed drug to identify uncommon adverse reactions and to obtain more information on incidence of reactions already indentified in clinical trails. In most countries we visited and in the United States, post-marketing surveillance consists of spontaneous reporting from physicians, hospitals, or manufacturers; and selected hospital monitoring. However, the United Kingdom, unlike most of the other countries, has a formal followup procedure for adverse drug reaction reports and is able to protect the confidentiality of the reporting source. Because of this, according to a United Kingdom drug regulatory official, participation by physicians is greater in the United Kingdom than in other countries.

Futher, this official said that the post-marketing surveillance reporting system has a positive effect on the drug approval process because it gives the regulatory agency more confidence in being able to accept a lower number of clinical trials in the testing stages of new drug development.

The proposed Drug Regulation Reform Act will authorize FDA to require manufacturers to establish and maintain a post-marketing surveillance system.

Acceptance of foreign data

If a country were to accept adequate and well-controlled studies from another country without domestic verification, it could result in earlier introduction of a drug in that country. However, the acceptance of foreign data, and the extent of domestic verification of this data, varies from country to country. Some countries—Norway, Netherlands, Switzerland—may accept foreign test data without domestic verification, depending on its source. Other countries—United States, United Kingdom, and Sweden—will usually request domestic verification.

FDA's policy for acceptance of foreign data has not always been clearly understood. Officials from 4 of the 8 companies we visited indicated that FDA would not accept foreign study data, and that safety and efficacy of a drug must be supported on the basis of duplicate domestic studies. FDA's Director of the Bureau of Drugs stated that FDA has had a reputation for not accepting foreign data for pivotal studies. However, the Deputy Director pointed out that since 1975 FDA's policy has been to place substantial weight on foreign studies as supporting evidence of a drug's safety and efficacy. In view of the misunderstanding of FDA's policy by some industry officials, we believe, FDA needs to clarify this policy.

United Kingdom has more flexibility

United Kingdom officials we interviewed indicated that their country is able to use more flexibility than the United States. We were advised, for example, that in approving a drug for marketing in the United Kingdom, the agency can restrict or limit the drug's use in a variety of ways. It may, for instance, limit the use of the drug to a hospital setting or restrict prescribing authority to certain types of medical specialists.

This flexibility, in our opinion, could enable the drug agency to authorize marketing of a drug which it might not otherwise be willing to approve without additional study.

Review of marketed drugs

The United Kingdom has appointed a panel of experts, the Medicines Commission, which periodically reviews marketed drugs to determine if it continues to be appropriate for those drugs to be on the market. The Commission reviews the country's experience with the drug and with any adverse side effects resulting from the use of that drug.

Thus, a drug, once licensed, does not necessarily remain on the market indefinitely without followup reviews. The United States does not follow a similar procedure.

Use of Computer Technology

We reviewed FDA's use of computer technology to assist reviewers in their NDA evaluations. FDA has access to 16 automated information systems containing information on (1) the review status and actions taken or pending on NDAs under review, (2) chemical structures of drugs already reviewed by FDA, (3) current and historical reports of adverse reactions to marketed drugs, and (4) scientific and medical articles on drugs.

Although some of these systems contain information that could facilitate the review and analysis of the large amount of data included with an NDA, most FDA reviewers we contacted are not using these systems. Few reviewers are aware of the automated information systems and what they contain. Reviewers told us they were aware of only 3 of the 16 systems. FDA has done little to increase reviewer awareness of computer support.

Also, reviewers generally did not participate in system design or development. Consequently, few automated systems support the drug review and approval process. Those that do, provide only marginal support. For example, one information system contains scientific information useful only to chemists. Animal or clinical test data useful to pharmacologists and medical officers are not available.

Because FDA's computer resources are not adequately used to support FDA reviewers, we believe FDA should

—evaluate the existing information systems to determine how they can better serve reviewers,

—make a survey of the needs of the reviewers that can be used in developing or redesigning information systems, and

—develop an education program for reviewers in the use of information systems.

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Food Safety and the Food, Drug, and Cosmetic Act (Delaney Clause)

AMA COUNCIL ON SCIENTIFIC AFFAIRS

The House of Delegates has considered the question of the Delaney Clause* and related provisions of the Food, Drug and Cosmetic Act pertaining to potential carcinogens used as food additives. A resolution adopted at its 1979 June meeting called on the AMA to "support the passage of legislation that would amend the Food Additive Act to require evidence based upon scientifically reproducible studies of the association of food additives with an increased incidence of cancer in animals or humans at dosage levels related to the amounts calculated as normal daily consumption for humans before removal from the market."

The Council on Scientific Affairs has also considered the problem of food safety on several occasions and has come to accept the suggestion that two central questions underlie the debate over the Delaney Clause:

1. Whether the scientific uncertainties that lead to the Delaney Clause have been resolved; and
2. Whether, failing scientific resolution, the public policy judgment made by the Congress in passing the Delaney Clause represents a currently appropriate decision for our society.

The first question is a scientific one; the second is a public policy determination.

Scientific Questions

At the time the Delaney Clause was incorporated into the Food Additives Amendment to the Food, Drug, and Cosmetic Act, there was scientific uncertainty about the potential carcinogenicity of most chemical substances. This uncertainty remains and the question has become more complicated. Some of the major concerns, then and now, are:

Mechanisms of Carcinogenesis. Although there is scientific consensus on some aspects of cancer induction, the means whereby carcinogens and carcinogen promoters induce malignant neoplasms in humans remain ill-defined. The relevance to human malignancy of benign tumors and hyperplasias observed in animal tests is also debatable. Many benign tumors remain constant in their biologic behavior; however, an increased incidence of benign tumors is often considered indicative of potential carcinogenicity.

Threshold Level. There is currently no scientific consensus on whether there is a threshold level below which no adverse response will occur. Although it is assumed that a threshold level exists for most biological effects, there are at present no biological data that confirm or refute the presence of a threshold for carcinogenesis. Moreover, there is currently no scientific consensus as to an appropriate method for calculating an acceptable daily or monthly tolerance for carcinogens.

Dosage Levels in Animal Testing. Although most scientists defend the statistical validity of using high test doses in bioassays, there is still much debate about using high dose levels that may subject the animal to physiologic stress. Many substances that cause cancer in animals at relatively high doses may not cause cancer in humans at the level of exposure expected with ordinary consumption of consumer products.

Applicability of Animal Data to Humans. Scientists accept, in general, the concept that positive test results obtained from animal bioassay systems may indicate potential carcinogenic risk for humans. However, all animals are not equally susceptible to known chemical carcinogens. While animal studies can often provide presumptive qualitative data, high dose animal tests may not adequately quantify the level of human risk.

Methods of Assessing Risks. As yet, there is no scientific consensus on the most appropriate method for quantitative risk assessment. Currently, a number of different proposals for assessing risk are under

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*The Delaney Clause: Federal Food, Drug, and Cosmetic Act, Section 409 (c) (A) (3) "No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive under the conditions of use to be specified in the regulation, will be safe: Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, . . ."

EDITOR'S NOTE: This is a report of the AMA Council on Scientific Affairs to the House of Delegates at its Interim Meeting in December 1979.

discussion. The National Academy of Sciences (2), the Food and Drug Administration (3), the Interagency Liaison Regulatory Group (4), and the Scientific Committee of the Food Safety Council (5) have all addressed proposed systems for risk assessment. Efforts to coordinate governmental regulatory actions with scientific estimates of risk in many areas, but particularly in the area of potential carcinogens, are currently under intense review.

The question "whether the scientific uncertainties that led to the enactment of the Delaney Clause have now been resolved" must be answered in the negative; few of the scientific concerns that underlie the Delaney Clause have been resolved. Furthermore, it is doubtful that these concerns will be resolved in the near future.

Public Policy Determinations

Because science has not yet been able to resolve the concerns that led to the enactment of the Delaney Clause, the appropriate basis for debate about this section of the Food, Drug, and Cosmetic Act becomes whether or not the public policy judgment made by Congress represents a currently appropriate decision for our society. Thus, the acceptability of the Delaney Clause, or its modification, becomes essentially a public policy determination.

The Delaney Clause (Section 409 (c) (3) (A)) of the Food Additives Amendment of 1958 prohibits the setting of tolerances for "food additives" that have been shown to induce cancer in man or other animals. It should be noted that "food additives" in this context is used to designate those substances added to food that are subject to the Delaney Clause. There are other substances added to food that are not legally defined as "food additives" and are thus not subject to the Delaney Clause.

This explicit anti-cancer clause and its companion in the Color Additives Amendment are corollary to the general food safety clauses of the Act; compounds, even when subject to the Delaney Clause, are also subject to the general safety clauses (402, 409, 701). For example, any use of an unsafe "food additive" is prohibited by section 402 (a) (1), the food adulteration clause, which states:

> "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity in such food does not ordinarily render it injurious to health."

Accordingly, this general food safety clause prohibits the use of a substance that has been determined to be unsafe.

The express anti-cancer clauses found in the Food, Drug, and Cosmetic Act, then, do not necessarily provide public protection greater than that already provided by the general food safety provisions of the Act; they are public policy statements relative to a specific hazard. Although the Delaney Clause and its companion clause in the Color Additives Amendment could be removed from the Food, Drug, and Cosmetic Act without diluting the potential protection provided by the Act, they have standing as a strong public policy mandate. Moreover, removal or modification of these clauses from the Food, Drug, and Cosmetic Act would not resolve all of the current public policy issues.

In many cases, prudence and concern for the public health might dictate the banning of substances from the food supply under either the Delaney Clause or the general food safety clauses. "Special case" exceptions for substances added to food, however, such as are requested for saccharin, are not permitted under the current Food, Drug, and Cosmetic Act. The question of saccharin and forthcoming issues illustrate the need for re-examination of the Food, Drug, and Cosmetic Act, especially the absolute terms of the Delaney Clause.

AMA Concepts of Food Safety Policy

The AMA should recommend that the Food, Drug, and Cosmetic Act be amended to allow for special case use of a food additive, despite its potential hazard, provided the perceived benefits outweigh the perceived risks. Another way of stating this is: the risk of using the substance is less than the risk of not using the substance. The first concept is termed the risk/benefit equation; the second is known as a comparative risk assessment or risk/risk equation.

Deliberations about amendments or regulations regarding the special case use of a food additive involve information about: the substance, proposed marketing conditions, and characteristics of proposed legislation or regulations.

The Substance

Several attributes of the food substance that are amenable to scientific assessment must be considered:

Usefulness. The substance is widely and frequently used so that a broad experience with it is available.

This allows some assurance of the adequacy of testimony about the substance. It also allows assurance that the substance is of sufficient importance that there is potential for harm to a part of the population if use of the substance is prohibited. Scientific and survey information can provide data on the use of the substance.

Function. Its use accomplishes a functional health purpose for which the special exemption is requested.

Saccharin, for example, would be considered to function as an effective sweetener.

Uniqueness. The same objective is not attainable by any alternative substances.

Saccharin, for example, would be considered unique because no comparable alternative non-nutritive sweetener is currently available. Vitamins and minerals used to fortify foods also satisfy the criterion of uniqueness.

Health Need. The health need for the substance has been established by appropriate documentation of scientific evidence and/or testimony of experts qualified by training and experience to make such judgments.

Health need would be considered a benefit to a segment of the population. Benefit, however, can be a perception that may be difficult to establish objectively. Expert decision making may be an appropriate mechanism to use in permitting some special case exemptions in a public policy decision.

Assessed Risk. The potential risk must be appropriately defined and shown to be sufficiently small by scientifically acceptable techniques to allow a favorable estimate of the risk.

The chemical nature and activity of the substance, acceptable animal test data, and appropriate human epidemiologic studies would, for example, be a part of this risk assessment. As newer tests or more refined assessments are established as valid, they would be incorporated.

Consideration of the above five points would permit a scientifically acceptable assessment of comparative risks and, in some instances, of a risk/benefit ratio. This should allow public educational efforts to be undertaken and appropriate warnings to be promulgated. It would provide the ability to propose and adopt restrictive measures short of absolute ban in special cases. This improved flexibility would allow agencies to propose, in the public interest, unique solutions for special case substances.

Proposed Marketing Conditions

Additional considerations in each special case for which limited marketing might be proposed could include:

Time Limit. The proposed modification of the Food, Drug, and Cosmetic Act for a special case exemption should permit marketing it for a specific time period only. Renewal of permission to market should not be automatic but require further inquiry.

The implied threat or explicit statement of future non-renewal could be used to stimulate the development of acceptable alternatives for a special case substance.

Restrictions. Permission to market the substance may need to be conditional or restrictive.

Conditions applied to the marketing of a special case substance should, on balance, constructively serve the objective of protecting the population at large or protecting the needs of a specific subpopulation.

Characteristics of Legislation or Regulations

To properly serve the public interest, modifications to the Food, Drug, and Cosmetic Act should be undertaken with great caution.

Construction. Modifications of current law to permit special case exemptions must be carefully drawn to prevent the incorporation of unimportant substances as special cases in the food supply.

Flexibility. Agencies should have the authority to propose and adopt measures that will allow the circumstances to fit the special case.

Providing agencies with the ability to propose unique solutions to problems would help assure the overall goal of protection of the public interest. Modifications to the Food, Drug, and Cosmetic Act should not preclude the convening of expert advisory panels, use of the Federal Register for public comment or other measures that allow the commissioner to determine the appropriate circumstances to fit each special case.

Recommendations

The Council on Scientific Affairs recommends that the AMA, through its Council on Legislation, develop alternative proposals in accord with the above comments to substitute for the Delaney Clause of the Food, Drug, and Cosmetic Act.

Even though the Council recognizes the political popularity of the Delaney Clause, it recommends that the AMA advise Congress that:

- The current Food, Drug, and Cosmetic Act limits the ability of regulatory agencies to exercise judgment and thereby make comparative risk or risk/benefit assessments for food additives as a part of the decision-making process.
- The Food, Drug, and Cosmetic Act should be amended to allow for consideration of the concept of alternative risks before requiring the banning of substances suspected of being hazardous.
- Eligibility of a substance for consideration by the regulatory agency as an acceptable food substance should be based upon the best scientific data available on the usefulness, function, uniqueness, health need for, and potential risk of the substance.

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Due Process

AMA COUNCIL ON MEDICAL EDUCATION

At the 1978 Annual Meeting, the House of Delegates asked that the American Medical Association support the acceptance by medical schools of adequate due process guidelines as a prerequisite for accreditation; that the Council on Medical Education develop model due process guidelines; and that the model be submitted to the Liaison Committee on Medical Education for inclusion in "Functions and Structure of a Medical School" as part of the standards for medical school accreditation. The Board of Trustees referred this to the Council on Medical Education.

The Council on Medical Education, the Liaison Committee on Medical Education and the Section on Medical Schools have studied Resolution 163 (A-78), *Board of Curators of the University of Missouri,* et al. v. *Horowitz,* 98 S. Ct. 948 (March 1, 1978), the United States Supreme Court decision referred to in Resolution 163 (a-78), and the *Preamble, Purposes and Principles* of the American Medical Student Association that includes due process guidelines for medical students. The following report is based upon these studies and the importance of striking a proper balance between the medical schools' responsibility to its governing body and society and the students' need to have the truth determined impartially and fairly once academic performance or conduct is questioned.

Supreme Court Decision

On March 1, 1978, the United States Supreme Court handed down an opinion in a case involving a student's dismissal from medical school prior to graduation. The Supreme Court held that (1) the student had been fully informed of faculty dissatisfaction with the student's clinical progress and the consequent threat to continued enrollment and graduation and was accorded procedural due process with respect to dismissal for academic deficiencies, notwithstanding the lack of a formal hearing; (2) academic deficiency dismissals do not necessitate a hearing before the school's decision-making body; and (3) the record revealed no showing of arbitrariness or capriciousness which would warrant remand of the case to a lower court for consideration of the question of deprivation of substantive due process.

The school had established a Council on Evaluation comprised of both faculty and students to evaluate on a periodic basis each medical student's academic performance. The Council could recommend various actions including probation and dismissal. Recommendations made by the Council were then reviewed by the Coordinating Committee of the medical school, a body comprised exclusively of faculty members. Ultimate approval of any recommendation was made by the dean of the medical school. Under the school's procedures, medical students were not typically allowed to appear before either the Council on Evaluation or the Coordinating Committee.

Under the facts presented to the Supreme Court, the student had been admitted to the medical school with advanced standing in the fall of 1971. In mid-1972, the student discussed with the dean of the medical school deficiencies in her performance. The problems were explained during the discussion and further notice of the student's unsatisfactory performance followed shortly after the discussion in the form of a letter from the dean. The dean met a second time with the student in October 1972, and in January 1973 the dean met with the student, her docent and the Chairman of the Council on Evaluation. At the January meeting, the student was notified of the Council's recommendation that she not graduate and be dropped from the school unless there was "radical improvement" in her "clinical competence, peer and patient relations, personal hygiene, and ability to accept criticism." The dean sent a letter to the student following the meeting summarizing the problem areas.

The Supreme Court found that these meetings and letters provided the "notice" of the charges required by the due process clause of the Fourteenth Amendment in student discipline cases. The medical school went

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EDITOR'S NOTE: This report, acceptable to the representatives of the Student Business Section and its delegate to the House, was adopted by the AMA House of Delegates at its Annual Meeting in July, 1979.

further by providing as a form of appeal to the student the opportunity to take a set of oral and practical examinations conducted by seven practicing physicians in the area so that independent recommendations could be considered. Two recommended graduation on schedule, two recommended that the student be dropped immediately from the school, and three recommended continuation on probation pending further reports on the student's clinical progress.

The Council on Evaluation met to consider these recommendations in mid May, 1973. The Council, on receipt of reports on two clinical rotations, unanimously reaffirmed its recommendation that the student be dropped from the school. The Coordinating Committee and the dean approved the recommendation and notified the student. The student appealed in writing to the University's Provost for Health Sciences who reviewed the record and sustained the school's actions. Suit was then filed to contest the dismissal on the grounds that the student's constitutionally protected rights of due process had been violated.

A majority of the Supreme Court Justices found that it was unnecessary to decide whether a student in a graduate professional school has a sufficient "property" or "liberty" interest in remaining a student to trigger the procedural protections of the Fourteenth Amendment. Assuming that such an interest existed, the Court found that the medical student in this case was afforded at least as much due process as the Fourteenth Amendment requires. The medical student was fully informed of the faculty's dissatisfaction with her clinical progress and the danger this posed to continued enrollment and timely graduation. The ultimate decision to dismiss was made carefully and deliberately and the medical school went beyond due process requirements in offering the student an opportunity to be examined by seven independent physicians in order to be absolutely certain that the faculty evaluation of the student's medical skills was correct.

One of the concerns the Supreme Court appeared to consider determinative was the importance of not placing undue burdens on the educational process. The Supreme Court noted that graduate and professional schools are the best judge of a student's academic performance and ability to master a required curriculum. To impose a full trial-type procedure with the presence of attorneys and the imposition of rigid rules of cross-examination at a formal hearing for a student appeared to the Court to serve no useful purpose. An "informal give-and-take" between a student and the administrative body that may dismiss a student, however, appeared to the Court to give the student an opportunity to characterize his conduct and put it in the proper context without unduly burdening the educational process.

Clearly, the Supreme Court Justices were seeking to balance the needs of students and professional schools and to find procedures that would be fair to both while still promoting the elusive goal of determining the truth in a manner consistent with both individual dignity and society's limited resources. The Supreme Court declined to further enlarge the judicial presence in the academic community and risk deterioration of faculty-student relationships. The Supreme Court noted that dismissal of a student on academic grounds requires expert evaluation of cumulative information that is not readily adapted to the procedural tools of judicial or administrative decision-making.

The Council on Medical Education and the Liaison Committee on Medical Education believe that these Supreme Court concerns are shared by both medical students and the medical school community. A proper balancing of the interests of the medical school and the medical student should be reflected in any guidelines developed to assure due process to medical students whose academic performance or conduct is subject to question and possible adverse action.

American Medical Student Association Model

In AMSA's model, medical schools would be urged to clearly formulate and communicate to students the jurisdiction of faculty or student judicial bodies and disciplinary procedures. The model states that: (1) the student's right to appeal a decision should be included in publications such as student handbooks or institutional regulations; (2) procedural fairness for accused students requires notice of the nature of the charges and a fair opportunity to refute them; and (3) pending action of the charges, the student's status should not be altered and the right to attend classes should not be suspended. The model would also urge medical schools to adopt the following guidelines for the development of hearing committee procedures to assure due process in disciplinary actions:

> "The hearing committee should include student members selected by the students. No member of the hearing committee who is otherwise interested in the particular case should be allowed to sit in judgment during the proceeding;
>
> "The student should be informed in writing of the reasons for the proposed disciplinary action with sufficient time to insure opportunity for preparation for the hearing;
>
> "The student appearing before the committee should be allowed to select an Advisor of his/her choice for assisting with his/her defense during the hearing;
>
> "The burden of proof must rest upon the officials bringing the charge;
>
> "The student should be given an opportunity to present evidence and witnesses on his/her behalf; and, hear and question adverse witnesses;
>
> "The student should be guaranteed the option to

> appear in either open or closed session before the hearing committee;
>
> "A complete transcript of the entire hearing should be recorded and kept on file for review by interested parties who have the written consent of the student;
>
> "In no case should the committee consider statements unless the accused student has been advised of their content and of the names of those who made them; and, unless the student has been given the opportunity to refute unfavorable inferences which might be otherwise drawn;
>
> "All matters upon which the decision is based must be introduced into evidence at the proceeding before the hearing committee;
>
> "The decision of the hearing committee should be final subject to the student's ultimate right to appeal to the highest governing body of the medical school."

This model incorporates the six basic requirements of due process which the students believe are essential for medical school actions that adversely affect a student's completion of the educational program, whether based on academic or nonacademic evaluations of performance; namely: (1) written notice of the charges; (2) student access to the "support data;" (3) the right to appear before the body charged with taking action; (4) the right to continue as a student during the review process; (5) the right of the student to request an appeal to the highest governing body of the school; and (6) full, voting membership by student representatives on the hearing body.

Liaison Committee on Medical Education

The following supplementary statements were adopted by the LCME at its October 16-17, 1974, meeting:

> *"Due Process*
>
> "A medical school should develop and publicize to its faculty and students a clear definition of its procedures for the evaluation, advancement, and graduation of students. Principles of fairness and 'due process' must apply when considering actions of the faculty or administration which will adversely affect the student to deprive him of valuable rights."
>
> *"Confidentiality of Medical Student Records*
>
> "In the spirit of fairness and 'due process,' there should be no secret record-keeping systems and the student should have appropriate access to his/her records, with the right to challenge the accuracy of the information contained therein. Moreover, with the exception of administrative officers, committee and faculty members of the medical school, the student's records are to be made available only upon written request by the student."

In June 1978, the LCME requested assistance in preparing a statement for distribution to medical schools for inclusion in their catalogs. This action would be consistent with the support for Resolution 163 (A-78) by the AMA Section on Medical Schools provided no reference to academic standards were to be included in the resolution.

AMA and Due Process

The AMA Judicial Council has established the following opinion on due process:

> "The basic principles of a fair and objective hearing should always be accorded to the physician whose professional conduct is being reviewed. The fundamental aspects of a fair hearing are: a listing of specific charges, adequate notice of the right to a hearing, the opportunity to be present and to rebut the evidence, and the opportunity to present a defense. These principles apply when the hearing body is a medical society tribunal or a hospital committee composed of physicians.
>
> "These principles of fair play apply to all disciplinary hearings and in any other type of hearing in which the physician may be deprived of valuable property rights. Whenever physicians sit in judgment on physicians and whenever the judgment affects a physician's reputation, professional status, or livelihood, these principles of fair play must be observed.
>
> "All physicians are urged to observe diligently these fundamental safeguards of due process whenever they are called upon to serve on a committee which will pass judgment on physicians. Medical societies and hospital medical staffs are urged to review the constitution and bylaws of the society or hospital medical staff to make sure that these instruments provide for such procedural safeguards."

The Joint Commission on Accreditation of Hospitals also subscribes to these principles of fair play and due process in the Standards and the Monograph on Medical Staff Bylaws.

The House of Delegates on a number of occasions has reaffirmed these principles of due process for its members and for the profession. The House adopted the position that these principles are applicable to residents in their relationships with hospitals at the 1974 Clinical Convention.

Also at the 1974 Clinical Convention, the House of Delegates adopted Report F of the Council on Medical Education on due process for medical students. In Report F (C-74), the Council on Medical Education reviewed the long standing concern by the Liaison Committee on Medical Education for the quality of the education program as a basis for accreditation to the exclusion of "social" or individual concerns which are subject to judicial remedies. The report further stated:

"At the same time, medical education includes the 'professionalization' of the student and it can be agreed that the rights of the physician with regard to due process apply to the student as a part of education for the profession. Indeed, due process applies to the student as an individual over and above his preparation for entry into the profession." The Council on Medical Education and the House of Delegates adopted the position that: "Principles of fair play and 'due process' must apply when considering actions of the faculty or administration which will adversely affect the student to deprive him of valuable rights."

Recommendations

The Council on Medical Education reaffirms its 1974 approval of the policy adopted by the LCME which states:

> "A medical school should develop and publicize to its faculty and students a clear definition of its procedures for the evaluation, advancement, and graduation of students. Principles of fairness and "due process" must apply when considering actions of the faculty or administration which will adversely affect the student to deprive him of his valuable rights."

In addition, to clarify and protect the rights of medical students, the Council on Medical Education recommends that:

1. Each school develop and publish in its catalog, student handbook or similar publication the institutional policies and procedures both for evaluation of academic performance, (promotion, graduation, dismissal, probation, remedial work, and the like) and for non-academic disciplinary decisions.
2. These policies and procedures should define the responsible bodies and their function and membership, provide for timely progressive verbal and written notification to the student that his/her academic/non-academic performance is in question, and provide an opportunity for the student to learn why it has been questioned.
3. These policies and procedures should also ensure that when a student has been notified of recommendations by the responsible committee for non-advancement or dismissal, he/she has adequate notice and the opportunity to appear before the decision-making body to respond to the data submitted and introduce his/her own data.
4. The student should be allowed to be accompanied by a student or faculty advisor.
5. The policies and procedures should include an appeal mechanism within the medical school.
6. The student should be allowed to continue in the academic program during the proceedings unless extraordinary circumstances exist, such as physical threat to others.

The Council on Medical Education further recommends that these principles be adopted.

Medical Education and Physician Supply

	1977-78	*1978-79*
No. of Medical Schools	124	125
Enrollment	60,456	62,754
No. of Freshmen	16,134	16,620
Women	14,373	15,293
Minorities	7,466	7,768
Graduates	14,393	14,966

437,000 physicians in U.S. in January 1979 . . . Ratio of non-federal MDs to population: 174 per 100,000 in 1976; 187 per 100,000 in 1978.

Total medical school enrollment and graduates doubled in 1960-1977 period.

87,069 Foreign Medical Graduates in U.S. in 1978. New provisions of Health Manpower Act reducing number. Total FMGs in housestaff positions in U.S. hospitals 10,188, down from 15,097 in 1976. One in five physicians in U.S. is FMG.

Total number of MDs certified by specialty boards: 192,629.

Significant downturn in *number of applicants* to medical schools . . . Peak was 42,624 in 1974; 36,636 in 1978-79. Still are far more applicants that can be accepted . . . Future projections show leveling off at 36,000 to 38,000 for next 8-9 years, then further decline.

A General Hospital Alcoholism Treatment Program

ALDEN E. WHITNEY, M.D., NANCY GRINDER, M.S.W.
AND RICHARD M. SALLICK, M.D.

ABSTRACT—The Norwalk Hospital Alcoholism Rehabilitation Program, founded in 1967, has developed a network of in-patient and out-patient services for the alcoholic person. The therapeutic program and its philosophy are described, showing how the patient, the family, medical personnel and recovering alcoholic volunteers function together to promote long-term arrest of the patient's disease.

The Norwalk Hospital Alcoholism Rehabilitation Program (NHARP) was born more than ten years ago through the efforts of recovered alcoholic laymen to bring acute treatment and rehabilitation planning for alcoholism to their general hospital. Although professionals have taken over its direction, the continued use of the recovered alcoholic volunteer keeps the layman integrally involved. The annual admission rate to this 427 bed hospital for the primary diagnosis of alcoholism increased markedly from 150 five years ago to 600 during the past year. Comprehensive alcoholism therapy is available to patients admitted to the psychiatric unit and to all medical and surgical units. Kinsella has discussed various treatment programs available to alcoholics in Connecticut hospitals.[1] We propose to describe the alcoholism treatment services which have been evolving at the Norwalk Hospital since 1967.

The adult or adolescent alcoholic suffers a chronic, progressive and potentially fatal condition characterized by multiple physical and psychological disturbances. In a recently published comprehensive discussion of the subject, Vaillant notes that "the clinician must learn to conceive of alcoholism as a 'disease' that causes depression, marital breakup, and unemployment, not a symptom that results from such distressing events".[2] NHARP focuses on the disease concept of alcoholism and several corollaries which spell out the philosophy of treatment. (1) Successful arrest of alcoholism requires abstention from ethanolic beverages and such substitutes as sedatives and minor tranquilizers. (2) In order to bring the patient to treatment, important people in his or her life (such as employer, spouse and children) must become involved in the constructive undermining of the patient's denial (alibi) system. (3) Therapy of the acute phases should be medical, but the long-term treatment, focusing upon education about the disease and upon eroding the denial and rationalization that possess all alcoholics, requires help from other professional and/or self-help programs. (4) Many patients benefit from a residential alcoholism rehabilitation facility for a two to six week duration following the acute hospital care period. (5) Medically supervised continuing care during the first year of abstention (sobriety) is provided through psychotherapeutic support from group treatment participation. (6) Help for the family is almost always necessary because the disease devastates his/her spouse and children as well as the alcoholic patient. (7) Long term association with Alcoholics Anonymous is the best overall support known at this time.

Although under Connecticut law those incapacitated by alcohol may be treated involuntarily up to 48 hours, the minimal admission requirements for the majority of patients are: to suffer alcoholism and to

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be willing to accept treatment. The usual route for entrance into the treatment program is by way of an in-patient admission to the Norwalk Hospital. Referrals come from a variety of sources including physicians, social service agencies, community agencies, sponsoring members of Alcoholics Anonymous, and patients themselves who have heard about the treatment program offered. NHARP maintains outreach offices in the South Norwalk community as well as in a hospital satellite medical clinic, and through allied alcoholism education and referral agencies.

Patients are admitted to 12 beds on the psychiatric unit or to 10 beds scattered throughout the medical wards. Those under treatment for other conditions, in whom alcoholism is discovered or reported by history, may be referred to the alcoholism nurse clinician who surveys the hospital at regular intervals looking for patients with alcoholism. She talks with the head nurses; she attends patient care planning sessions and offers formal instruction to the medical and surgical nursing personnel. Her efforts have been instrumental in increasing the sensitivity of the staff nurse as well as by decreasing his/her prejudice regarding the alcoholic. The understanding nurse subsequently puts more than the usual pressure on the physician to encourage his patient to participate in alcoholism therapy.

Hospital In-Patient Treatment

The hospital treatment program can be conveniently divided into subsections labeled (1) acute care and medical evaluation and (2) confrontation/education/ and rehabilitation planning. The regimen for alcohol withdrawal utilizes chlordiazepoxide as a longer lasting substitutive tranquilizer, magnesium sulphate as an additional anti-convulsive measure, and multi vitamins. The chlordiazepoxide schedule is routinely scrutinized in order to determine the progression of the withdrawal state, avoiding unnecessary oversedation or in the case of undertreatment, avoiding potentially fatal delirium tremens. The internist or family practitioner who participates in every treatment case evaluates the patient for various physical manifestations of alcoholism. Care is taken to discern those patients who have additionally abused sedatives or minor tranquilizers . Patients with a hidden history of pill abuse may suffer an otherwise unexpected seizure after alcohol withdrawal has been completed. Patients who are known to have suffered withdrawal or other epileptic phenomena in the past are additionally treated with phenytoin. Any "first seizure episode" even though probably due to alcoholism, calls for a neurological workup, and a subsequent seizure episode generally does not.

Alcoholism is found to be a significant factor in up to 40% of Norwalk Hospital patients admitted for suicide attempt. Not a few patients with depression or psychosis are found to suffer a combination of alcoholism plus schizophrenia or alcoholism plus manic-depressive disease. These patients do well in the milieu of the psychiatric unit where coincidentally the major portions of the alcoholism education and therapy occur. Not infrequently, a hospital stay that commences with treatment for psychosis or suicide attempt ends with education about and referral planning for long term alcoholism arrest. Many patients who suffer primary alcoholism experience depression. Comprehensive therapy for alcoholism is usually sufficient and we postpone psychiatric intervention until several months of abstention and alcoholism therapy have failed to relieve the affective component.

Disulfiram offers an additional deterrent to the willing patient who may drink impulsively or may obsess constantly about whether or not to drink. Taking disulfiram once a day represents a decision not to drink, and may be used effectively if the patient is also willing to participate in alcoholism group therapy and/or Alcoholics Anonymous. It is not routinely prescribed by us for the new patient, but is often recommended to the relapser who can understand the possible dangers, and who is neither psychotic nor suicidal.

The education/confrontation/rehabilitation planning segment of treatment begins at the outset of the admission interview. All members of the psychiatric nursing staff are thoroughly familiar with alcoholism as a disease entity. They expect each patient to be fearful and denying. They know how to answer the patient's demands in a way that capitalizes on the fact that most patients are best motivated by education and commitment to accepting help during the acute stages of withdrawal. On the medical and surgical services as well, many nurses understand the need for compassionate yet firm undermining of the patient's denial (alibi) defenses. Daily offering of educational group meetings includes lectures, films and discussions concerning the facts about alcoholism, the nature of alcohol as a depressant addicting drug, the symptoms and signs of the disease, and the therapeutic methods necessary to achieve total abstention from alcohol and sedative and minor tranquilizing drugs. Individual counseling and daily group therapy sessions deal with the special problems of each individual, but patients are encouraged to view themselves as ordinary people suffering ordinary ("garden variety") alcoholism. Group therapy provides the individual patients with an opportunity to identify himself as one of a large group of people suffering a common illness. Crucial to this identification process is the involvement of recovered alcoholic volunteers who have maintained at least two years of continuous sobriety in association with Alcoholic

Anonymous participation. Several volunteers are present every morning and evening to talk to the patients and to take them to five meetings of AA weekly. Wherein involvement by a patient's family and employer may increase the motivation toward health, the role model function of the volunteer offers the hope without which the patient may give up on participation in therapy.

The average length of stay for uncomplicated detoxification and rehabilitation planning is 6.3 days.

Residential Rehabilitation

Residential rehabilitation for two to six weeks following hospital admission is arranged for a majority of patients. Facilities in the nearby Connecticut or New York state areas are used for the most part; but to fit the special need of the individual, alcoholism rehabilitation facilities throughout the United States are utilized. The programs offer a sheltered stay away from alcohol, home and a job, during which the alcoholic learns more about his "disease" and making his recovery Number 1 on his priorty list. Many facilities offer concomitant alcoholism education and therapy for family members. The spouse and/or children of the alcoholism sufferer are always seriously affected by the behavior of the drinker. For this reason, Norwalk Hospital offers a weekly orientation/information meeting for the public in general, as well as a group therapy session for the family members of in-patients in the alcoholism treatment program in particular. When backed by solid information, the spouse and children can accept the support offered by the hospital of their own efforts to confront the denial of the alcoholic and in an equally important fashion to understand and to uphold the alcoholic when he does make efforts to accept treatment and to do his part in it.

NHARP counselors track each patient after discharge to a residential facility or home attempting to enroll as many patients as possible for long-term therapy. Especial care is taken with patients refusing recommendations or signing out of the hospital prematurely (at the rate of 25%) before plans can be offered.

Continuing Care

The newly sober alcoholic requires long term continuing care. While all patients are directed toward Alcoholics Anonymous, they are offered a supplement or a temporary alternative to AA in an assignment to one of eight out-patient rehabilitation groups meeting weekly—with the expectation that each patient will participate in the meetings throughout the first year of sobriety. The staffing for the group leadership includes two psychiatrists, one social worker, a nurse, five alcoholism counselors, two counselors in training and numerous volunteers who are members of Alcoholics Anonymous. Each group enrolls no more than 15 members. After the first year of sobriety there is special long term group support for patients who have second diseases, such as schizophrenia and manic-depressive illness. Patients who present problems of chronic relapse are placed in separate therapeutic groups so that they may get extra attention. This avoids dilution of the strong motivation present in the eight regular therapy groups.

NHARP acts as an effective interface between the hospital and the community. Its downtown office in South Norwalk provides consultation and education in pleasant surroundings which offer a drop-in center for all patients. A job expeditor assists clients to find employment as an integral part of recovery. A social worker directs the overall operation and, in addition to supervising alcoholism counselors, sees a number of patients for long term counseling and psychotherapy. One alcoholism counselor leads a group for wives of alcoholics who meet in order to support one another in attempting to bring the still drinking alcoholic spouse into treatment as well as to prevent further deterioration of the family. Individual consultation and group therapy are offered in a Norwalk community center which serves the Black community. Spanish-speaking counselors are available in the same manner for the Puerto Rican and Latin American population of the hospital catchment area. The hospital sponsors three distinct AA meetings, including one where only Spanish is spoken.

Successful alcoholism rehabilitation programs are most effective when they offer a wide spectrum of services to the patient and the family, addressing the medical, psychological, interpersonal, and vocational needs of one or more members of the family, as well as of the alcoholic. Norwalk Hospital provides in-patient short term and out-patient long term programs. NHARP's good relationships with residential rehabilitation facilities, halfway houses, alcoholism councils in surrounding communities, and the social and welfare agencies of Norwalk are indispensable for completing the treatment armamentarium we can offer. One of the gratifying results of NHARP is the continued success of the volunteer program in attracting former patients after two years sobriety to work in the hospital by sharing their experience and hope with the still suffering alcoholic.

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Month in Washington

Soviet military adventuring, growing debate on the strength and readiness of our armed forces, and a presidential election to boot augur little attention to matters of medicine and health by the second session of the 96th Congress. But Capitol Hill soothsayers have not always been correct.

Deep within the president's State of the Union message he asks the Congress to approve his plan for national health insurance, stating it is "—the solution to the thirty years of congressional battles on national health insurance." The president also urged the Senate to rescue his hospital cost containment proposal, declaring the "longer we delay enacting cost containment, the more expensive our fight against hospital inflation will become."

Towards the end of the month the president spelled out in his budget message more details of his administration's thinking with respect to the direction of the federal government's health policies.

* * * *

The Carter Administration has asked Congress to approve a $61 billion budget for health programs, $5 billion more than last year, largely because of the climb in the costs of Medicare and Medicaid.

The budget for fiscal 1981, the year starting Oct. 1, was marked by "overall fiscal restraint" due to the exigencies of inflation and international confrontations, but most health programs were ticketed for modest increases. The notable exception was aid for medical education, where the administration again proposed eliminating capitation aid and reducing funds for nurses' training.

A renewed plea was made for passage of President Carter's National Health Plan, but significantly, no start-up funds were set forth in the budget.

The administration also optimistically assumes that Congress will approve the Hospital Cost Containment Act (with a claimed result of annual "savings" of $700 million) despite House defeat last year.

The Health, Education and Welfare Department asked for a total of $222.9 billion, of which $153 billion represented Social Security disbursements and $51 billion was for Medicare and Medicaid outlays, up $5 billion.

The budget contained $326 million for support of health professions training programs, but states that by 1990 the supply will exceed the need, especially in the case of physicians. The termination of capitation grants to medical schools, a fiscal body blow to the schools, would be accompanied by a $77 million cut in support of nurse education.

The administration's new health manpower program hasn't been sent to Congress as yet, but the lawmakers probably won't have time to act this year and may pass a one-year extension of existing aid.

The budget provides a $17.7 million increase, for a total of $83.2 million, for expanded programs to train primary care physicians.

An additional 765 new and converted first-year family medicine residencies will be created nationally, bringing the total to 3,265. Also proposed are 147 new first-year residencies in other primary care specialties such as general internal medicine and general pediatrics.

Support for direct health services in community health centers and migrant health centers would total $436 million, an increase of $54 million.

The budget for the National Health Service Corps (NHSC) would total $134 million, an increase of $52 million. This would swell the present Corps by 1,700 so that 4,500 health care professionals would be serving. At the same time, the NHSC scholarship program, with an additional $8 million, would be providing $94 million in support of 6,700 students who later would join the Corps.

Funds for the maternal and child health grants to states and family planning programs were set at $537 million, a $27 million increase.

A total of $565 million was earmarked for the Indian Health Service, a $50 million increase.

The administration is requesting $69 million—a $10 million increase—to support 36 new Health Maintenance Organizations (HMOs) and to expand 47 existing HMO plans.

The president's budget request for all mental health activities in 1981 is $671.3 million, including $367,775,000 for services, $162,964,000 for research, $90,354,000 for training, $12,117,000 for formula grants to states and $38,113,000 for program administration.

The Medicare and Medicaid programs would be expanded. Legislation will be sought to eliminate the Medicare requirement that beneficiaries be hospitalized for three days before they are eligible for home health care services. Funds were proposed for a

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Prepared by the Washington, D.C.
Office of the American Medical Association

Medicare demonstration project to determine the costs and practicality of payment to home health aides for providing routine homemaker services, in conjunction with home health care.

The overall Medicare and Medicaid budget request for 1981 is $53.2 billion, an increase of $5.4 billion. The budget proposal includes $403 million to fund the Child Health Assurance Program (CHAP) now under consideration in the Congress. CHAP would extend health care to an additional two million poor children not now eligible for Medicaid.

Expanded services to migrant children and to poor children in urban areas would result from a proposed $90 million increase in the budget for the Head Start Program.

The budget targets $859 million for the Public Health Service to promote healthful lifestyles, provide preventive health services and protect consumers and persons in the workplace, an increase of $87 million.

The National Institutes of Health budget is $3.6 billion, up $139 million. Only minor additional funds were sought for the 11 institutes. The National Cancer Institute continues to get the most, $1 billion, with Heart, Lung and Blood next at $548 million.

* * * *

The administration plans to amend its National Health Plan to eliminate the requirement that reimbursable chiropractic services can be provided only on referral from physicians.

Stuart Eizenstat, Domestic Affairs Aide to President Carter, told the American Chiropractic Association and the International Chiropractors Association in a letter that "the initial specifications for the Administration's legislation were altered to provide a definite role for chiropractors" following talks with chiropractic officials.

HEW will soon be sending Congress a technical amendment to provide chiropractors a greater role in the plan, according to Eizenstat.

The Medicare-Medicaid amendments being considered in the House and Senate also relax requirements for chiropractic reimbursement. The House measure changes present requirements by reimbursing chiropractors for the costs of X-rays to diagnose subluxation of the spine. Reimbursement also is allowed if subluxation is demonstrated through clinical finding without X-ray. The Senate bill follows the latter provision, simply dropping the requirement for X-ray to demonstrate subluxation.

* * * *

American physicians have chalked up a "massive accomplishment" in keeping medical fees below the Consumer Price Index (CPI) in a time of galloping inflation, according to James H. Sammons, M.D. executive vice president of the AMA.

Physicians "have clearly demonstrated their intention to make the Voluntary Effort (VE) work," Dr. Sammons said. "We are going to continue to expand our best efforts," he pledged.

Commenting on the impact of the VE since its 1977 inception, Dr. Sammons told a Washington, D.C. news conference the results mark "a rare occasion in history, when a professional group has voluntarily restrained the rate of increase in its fees. They now stand three percentage points below the CPI." The achievement is all the more noteworthy in view of the fact that the buying power of physicians has dropped 10 percent in the past eight years, he said.

Figures released at the briefing showed that the nation's hospitals have saved consumers more than $2.88 billion since the VE was established and that during most of this period the rate of increase in physicians' fees has consistently been several points below the all-items index of the CPI. Price increases throughout the health care field have been more moderate than the overall CPI. The latest statistics show that the medical index was lower than the overall CPI for the 13th month in a row.

Paul Earle, VE executive director, said the VE goals include a continued campaign to restrain the increase in health care costs to attain a closer relationship between total health care expenditures growth and growth in the total gross national product.

The national increase in total inpatient community hospital expenditures in 1980 should decline by 1.5 percentage points from 1979, contingent on no increase in the general economy-wide inflation rate in 1980 over 1979, he said.

The total number of hospital beds in the nation should be held at the level as of December 31, 1978, adjusted for any new beds added due to certificate-of-need approvals prior to that date.

The latest data show hospital beds increasing at the slowest rate (0.7 percent for the first nine months of 1979) since 1963, the first year for which data are available.

Physicians, during the first half of 1980 were asked to continue to voluntarily restrain fee increases to a level that maintains the 1979 relationship between the all-items index and the physicians service index of the CPI. This target will be reassessed in mid-1980.

The VE founding members are the AMA, the American Hospital Association, and the Federation of American Hospitals. In addition to these three organizations, the VE partners include the Blue Cross/Blue Shield Associations, the Health Industry Manufacturers Association, the Health Insurance Association of America, the National Association of Counties, representatives of business, and Virginia Knauer & Associates, a consumer affairs consulting firm.

* * * *

Reflections from the Dean's Office

Fides Medici (Continued)

ROBERT U. MASSEY, M.D.

> "For my Religion, though there be severall circumstances that might perswade the world I have none at all, as the generall scandall of my profession, the naturall course of my studies, the indifferency of my behaviour, and discourse in matters of Religion, — ,"

so Thomas Browne, M.D., begins his *Religio Medici,* the charming essay about God and man which in the preface he says he had written "for my private exercise and satisfaction", but which in its Augustan prose continues to speak to the world as clearly today as it did more than three centuries ago on matters of faith and tolerance.

Browne wrote another book, *Pseudodoxia Epidemica,* more often known then and now as *Vulgar Errors,* in which he affirmed his faith in observation and reason, in the new learning of Bacon, and in experimental science. Reason, faith, and careful observation of nature could never, in his view, be at odds in any essential way because they shared a common Author, though there might sometimes be a problem with Scripture, and "Galen doth sometimes nibble at Moses." Browne's science strikes us at times as quaint; he believed in the existence of centaurs because travelers had seen them, and he had difficulty in accepting the proposition that the earth moved even after Galileo had affirmed it. He admitted, though, that he might be persuaded, and he did accept Harvey's proof of the circulation of blood. He was a seventeenth century man standing with one foot on the threshold of the modern world which the new learning had begun to disclose, and he was willing to trust that observation and experimentation could be part of the substance of his faith. That faith is still the *Fides Medici* today.

Several years ago, Norman Cousins wrote "Anatomy of an Illness";[1] this has now been republished in book form along with some essays on healing, the placebo, longevity, pain, and holistic healing.[2] He writes as a layman from a standpoint outside medicine, but not apart from it, about his own illness and recovery, as well as about how in others the affirmation of life has made for healing and longevity. He writes of those matters known by good physicians from long before the new learning: that the mind has much to do with health and sickness, healing and recovery, and length of life; that good humor goes with good health, and bitterness and depression are often the forerunners, and perhaps the cause, of serious organic disease. This is knowledge drawn from a hundred clinical observations; its truth and its importance cannot be set aside merely because we have not yet discovered the mechanism. Perhaps we never shall.

But because these matters have not been reduced to science, because they have not been quantified and explained even as well as Harvey measured and explained the circulation of the blood, they are not practical in the same way. When we must manage diabetic ketoacidosis or acute leukemia, these insights, important as they are in elucidating the setting in which illness occurred, cannot be used to effect a cure or extend a life. For half the world's population, the keys to health are better nutrition, mosquito control, and immunization. When the chips are down and a predictable outcome is the only one that will do, the physician turns to his technologies, and speculation about the *vis mediatrix naturae* is saved for a quieter time.

Of course, he knows that he is seeing only a piece of the truth, but a useful piece for now. Later, observations on how the mind effects healing may be incorporated into larger theories about consciousness and nature. But the physician cannot abandon his faith in the scientific method. As with Browne, that is a central piece of his *religio.* Cousins agrees:

> "It is reasonable to expect the doctor to recognize that science may not have all the answers to problems of health and healing. But it is not reasonable to expect him to give up the scientific method in treating his patients."[3]

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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EDITORIALS

Diagnosing the Solitary Pulmonary Nodule

Every physician is faced from time to time with a chest x-ray revealing a "coin" lesion which means a roughly spherical shadow of even density 1 to 6 cm. in greatest diameter. The patient is without chest complaint in over 80% of such instances and the physician needs to resolve the question; benign?, primary cancer?, secondary malignancy? Current five-year salvage rates for asymptomatic lung cancer are better than 50%, whereas fewer than one in five are saved once symptoms occur.[5] So, prompt establishment of the nature of the lesion in the lung is a vital professional duty.

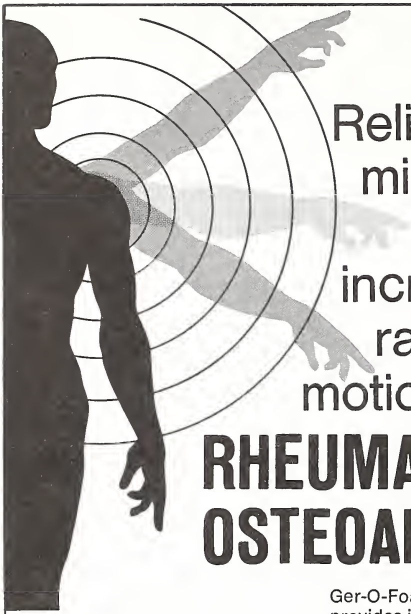
Skin tests for tuberculosis, coccidioidomycosis, or histoplasmosis if positive do not per se identify a pulmonary infiltrate as such an infection. When calcification is central within the lesion, or the person has spent considerable time in the southwest and has had a pneumonic episode in the past, a diagnosis of coccidioidomycosis is justified. The only really specific radiographic characteristics of a granuloma are a truly central nidus of calcification or onion skin rings that may or may not be calcified. Another benign condition is hamartoma. There may be peppercorn calcifications. Hamartomata grow and vary in diameter from one to eight centimeters. Arterio-venous malformations may be accompanied by blemish on lip or tongue, may be multiple and can be diagnosed by pulmonary angiography. The study of the x-ray is best served by an orderly sequential approach. Comparison with prior chest x-rays is vitally important to determine change in size, shape, and rate of growth. Securing old x-rays demands patience, fortitude, and at times a detective's skills on the part of the physician and his staff. When you can demonstrate that a supposedly new-found coin is unchanged in five years, the sense of relief is tremendous.

Full chest tomography in two planes at one centimeter intervals can satisfy the desire to identify additional pulmonary pathology,[1] especially if there is any suspicion of metastasis. Patients who have concurrent or prior cancer are suspect, but for others, I believe that better radiographic viewing of the undiagnosed lesion should precede whole chest tomography because of the latter's expense.

At present CT scans at two-second exposures will add quantity to parenchymal nodules found, but does not provide good discrimination in the local tissue.[5] Identification of the intimate characteristics of the nodule may be obvious in high quality chest radiographs. Rigler crescent on the hilar aspect of the nodule or an associated hilar node enlargement strongly point towards cancer. Small film polygraphic planography centered over the lesion and with two millimeter cuts can bring out minute calcifications, cavities, and particularly differentiate the absolutely smooth border of granuloma, inspirated mucus, or fluid-filled cyst from the always slightly irregular margin of any cancer or hamartoma. The vessels related to A-V malformation may also be made apparent.

Suspicion of cancer in a coin lesion demands that the true diagnosis be established. Sputum cytology is worth trying after thorough patient instruction even though less than one third of peripheral nodules will be "positive."[6] Bronchoscopy under fluoroscopic guidance with brushing and washings will identify better than half peripheral cancers. The skill, experience and patience of the operator is most important to success.[2,4] When surgical risk is minimal, exploratory thoracotomy and appropriate wedge, segment, or lobe removal is appropriate.

When operative risk is high, or the radiographic consensus is somewhat against cancer, or the patient is reluctant to undergo operation, the physician can offer a waiting period and re-examination. More than four weeks' delay seems unjustifiable to me when we can so closely correlate percentage survival with tumor diameter both for primary lung cancer and solitary metastasis.



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The entire thrust of medical knowledge remains for now towards removing cancer whenever found, as soon as reasonably possible. While some benign lesions will be operated on unnecessarily, an orderly and thorough study of each person harboring a solitary pulmonary nodule will ensure that salvage is offered to as many cancer victims as possible.

John L. Pool, M.D.

Wilton, CT

Consultant surgeon, Memorial Sloan Kettering Cancer Center, New York; Chairman, Professional Education Committee, American Cancer Society, Connecticut Division, Wallingford, CT.

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Letters to the Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed by all authors, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.

AN OPEN LETTER TO A PATIENT

To the Editor: Several weeks ago you confronted me with the following problem. I had removed your appendix as an emergency procedure and you had been discharged from the hospital without complications after five hospital days. You carry insurance coverage in the form of Connecticut Blue Cross "semi-private" insurance and CMS Century 90 which is now Blue Shield of Connecticut. At this point, you had found that your entire hospital bill had been paid by your Connecticut Blue Cross but that my surgical fee was only slightly more than half paid by your CMS Century (Connecticut Blue Shield) insurance coverage. You wondered if there was not some sort of mistake and so did I. In any event, I told you that I would look into the problem and get back to you with some answers.

I personally carry the same Blue Cross-Blue Shield coverage that you do and have for over twenty years. I confess that I have not kept track of what has happened to the cost of premium payments nor the scheduled allowances paid by these insurances.

It so happens that I have in my office CMS (Blue Shield) allowance schedules going back to 1968 as well as the newest "update" of July 1, 1979. I have, therefore, arbitrarily taken 1968 as a base year and have gotten from our hospital, Blue Cross approved hospital room rates, average semi-private, starting in 1968 also. In my personal files, I have looked up my Blue Cross, CMS premium receipts again since 1968.

I have found that since 1968 our hospital semi-private room charges approved and paid by Blue Cross have increased 114%. Please remember that our hospital has one of the lowest room rates in the state. Our Blue Cross premiums have risen 154% since 1968. The CMS schedule of allowances for Appendectomy has only risen 69½% since 1968 although CMS premiums have gone up 200%.

My surgical fees, based on usual and customary charges that prevail in the general area, have also risen since 1968 for Appendectomy but only 103%. This is much less than the overall medical consumer price index rise since 1968.

I think these figures show at whose door the problem lies and perhaps we need to ask Blue Shield why.

John M. Hoffer, M.D.

Ansonia, CT

POLICE TESTING

To the Editor: In their recent article in *Connecticut Medicine* on "Police Testing and Informed Consent," Attorneys Eisner and Rabkin conclude that they found "no Connecticut case law or statute which authorizes a private physician to take a blood sample on the request or order of the police without the consent of the person who is to be tested." While the article goes on to consider in detail the admissibility of such evidence and the nature of informed consent that is required, and the capacity of someone to give consent, they conclude that these tests should not be performed at the request of the police or prosecutor unless the physician has obtained the consent of the person who is to be tested.

While I do not think the authors intended to imply that diagnostic measures could not be made for treatment purposes, I think it is a conclusion that might be drawn from their article as they only note at the end that an "emergency" obviates the need for consent. In addition to emergency situations, I believe the physician does have statutory authority to perform blood tests on a person who appears to be "incapacitated" by alcohol. This authority is derived from Section 17-155v of the Connecticut General Statutes. Section (a) states that "Any police officer finding a person who appears to be incapacitated by alcohol shall take him into protective custody and have him brought forth with to a medical facility . . .". Section (b) continues "A person who comes voluntarily or is *brought* to a licensed treatment facility or other medical facility, SHALL BE examined by a medical officer or his designee as soon as possible. The medical officer shall determine whether the person requires inpatient treatment based on the medical examination of such person and upon finding that such a person is incapacitated by alcohol. Such medical officer may employ any diagnostic or therapeutic procedures reasonably necessary to restore the person to a state of being no longer incapacitated by alcohol."

It seems to me, under this statute, both the police officer and the physician have a duty. For the police officer the duty is to transport such a person to a medical facility, and for the physician, the duty is to examine and to ascertain whether or not such a person is incapacitated; and in order to do that, any diagnostic tests may be performed.

"Incapacitated" in the statute is defined as meaning "a condition in which a person, as a result of the use of alcohol, is unconscious or has his judgement otherwise so impaired, that he is incapable of realizing and making a rational decision with respect to his need for *treatment.*" The implication of this to me is that it is only necessary for the police officer to conclude that the person *appears* to be incapacitated. Once he so concludes, then the physician is authorized to be able to perform such diagnostic tests. Thus, no emergency need exist.

The authors imply that the physician might not be authorized to evaluate this person medically if, facing criminal charges, the patient refused blood tests. It is clear from the above definitions that this would not be an acceptable basis for refusal. The criterion for informed consent in this situation would be that the patient was incapable of making a rational decision only with respect to his need for *treatment,* and not in regard to any possible criminal proceeding. The patient seems adequately protected in court from having this evidence introduced as the article indicates.

Certainly the ethical issues here are complicated. The boundary between the physician's role as social control agent or as healer is often more blurred than we would like to think. In this circumstance, physicians have the discretion to order tests in less than emergency situations, if they conclude that it is medically indicated.

Howard V. Zonana, M.D.
Associate Professor of Clinical Psychiatry

Yale University
Department of Psychiatry

The above letter was referred to Attorneys Eisner and Rabkin who offer the following reply:

To the Editor: This is in response to Dr. Zonana's letter in which he cites Section 17-155v of the Connecticut General Statutes. This section is not relevant to our article, "Police Testing and Informed Consent," which deals with testing at the direction or for the benefit of law enforcement officials.

Section 17-155v is part of Chapter 304c of the Connecticut General Statutes which concerns drug and alcohol abuse. Section 17-155v and related sections were intended to "decriminalize" alcoholism. In no way does Chapter 304c authorize medical personnel to take tests at the direction or for the benefit of the police or the prosecutor. Section 17-155v(a) provides that the detained person is not to be considered under arrest, and no record is to "be made to indicate that the person has been arrested or charged with a crime." The person may be examined by medical personnel, and, if found to be incapacitated by alcohol, may be treated to remedy such incapacity. Under appropriate circumstances, commitment procedures may be instituted. Section 17-155bb(b) provides that the person's "identity, diagnosis, prognosis or treatment" is to be kept confidential in accordance with the requirements of the federal statutes and regulations concerning the confidentiality of alcohol and drug abuse patients' records which we refer to in footnote 4 of our article.

We emphasize that if the provisions of Chapter 304c are misused to permit tests at the direction or for the benefit of the police or the prosecutor, then the medical personnel and the law enforcement officials involved all will face possible civil and criminal liability for their conduct.

J. Michael Eisner, Esq.
Judy A. Rabkin, Esq.

Wiggin and Dana
New Haven, CT

STRESS TESTING AS A SCREENING PROCEDURE

To the Editor: It has become a practice in the past few years for several hospitals in the State of Connecticut to promote stress tests as a screening procedure for detecting occult coronary artery disease. These programs have been advertised through direct mailing and articles printed in the newspapers.

The Connecticut Society for Internal Medicine has opposed this practice and introduced a resolution at the annual meeting of the American Society of Internal Medicine, in this regard. The resolution was unanimously passed. This philosophy has been strongly endorsed by the Connecticut Affiliate of The American Heart Association.

There is no question that stress testing has a valuable role in the practice of medicine. It is also an accepted reality that stress testing is not without dangers, and sudden death does rarely occur. Because of the frequency of false positive and false negative tests when done as a screening procedure in the general public, the cardiac literature does not support exercise testing as a screening procedure, and, in fact, suggests needless and serious psychological damage may ensue from this practice.[1-5]

The superlatives of the stress testing screen and positive beneficial effects are emphasized in the advertisements mailed to the public and in the articles printed in the media. There is no mention of any physical hazards nor psychological trauma inherent in the methodology. The public, for whom this promotion is intended, is not given privy to available knowledge. This, in my opinion, violates the concept of informed consent.

It is generally accepted that a careful history is a far more important means of screening than a stress test. This, I believe, is a truism for most medical problems. It is obvious from the magnitude of the tests performed in the assigned time this is impossible, and, in fact, it is well documented that this does not occur.

It is suggested that should these institutions insist on their right to continue this program based upon differing opinion, that written permission from the private physician be obtained. In the event that there is none, it is suggested a vocal comprehensive history be taken by the cardiologist in charge or other qualified physicians, and that this be submitted in writing.

Edward H. Scherr, M.D.
President-Elect

Connecticut Society of Internal Medicine
New Haven, CT

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Summary of Decision Upholding Right of Nonsmoking Office Worker

Occupational Safety

Employer's refusal to enact work place smoking ban denies nonsmoking employee who is severely allergic to gases produced by burning cigarettes her common-law right to safe working environment.

This case involves a matter of first impression in New Jersey: whether a nonsmoking employee is denied a safe working environment and is entitled to injunctive relief when forced by proximity to smoking employees to involuntarily inhale "secondhand" cigarette smoke. The nonsmoking employee has a severe allergic reaction to cigarette smoke. She alleges that her employer, the N.J. Bell Telephone Company, is causing her to work in an unsafe environment by refusing to ban smoking in the office where she is employed.

It is clearly the law of New Jersey that an employee has the right to work in a safe environment. An employer is under an affirmative duty to provide a work area that is free from unsafe conditions. This right to safe and healthful working conditions is protected not only by the duty imposed by common law upon employers but also by the Occupational Safety and Health Act, 29 U.S.C. § § 651-78. OSHA in no way preempts the field of occupational safety. 29 U.S.C. § 653 (b) (4) recognizes concurrent state power to act either legislatively or judicially under common law with regard to occupational safety.

The nonsmoking employee has a common-law right to a safe working environment. The issue remains whether the work area here is unsafe due to a preventable hazard that the court may enjoin. There can be no doubt that the byproducts of burning tobacco are toxic and dangerous to the health of smokers and nonsmokers generally, and to this employee in particular.

The national policy to warn the public of the dangerous nature of cigarette smoke, as expressed in the Public Health Cigarette Smoking Act, 15 U.S.C. § § 1331 et seq., has made that fact generally acceptable. The court takes judicial notice of the toxic nature of cigarette smoke and its well-known association with emphysema, lung cancer and heart disease.

The HEW Report for 1975, The Health Consequences of Smoking, indicates that the mere presence of cigarette smoke in the air pollutes it, changing carbon dioxide levels and effectively making involuntary smokers of all who breath the air. Prior to this report, it was generally accepted that smoking is a hazard voluntarily undertaken. The opinion that tobacco smoke should be eliminated from the work environment is shared by allergists, immunologists and specialists in the field of industrial medicine.

The evidence is clear and overwhelming. Cigarette smoke contaminates and pollutes the air creating a health hazard not merely to the smoker but to all those around the smoker who must rely upon the same air supply. The right of an individual to risk his or her own health does not include the right to jeopardize the health of those who must remain around him or her in order to properly perform the duties of their jobs. The portion of the population that is especially sensitive to cigarette smoke is so significant that it is reasonable to expect an employer to foresee health consequences and to impose upon the employer a duty to abate the hazard causing the discomfort.

The employees' right to a safe working environment makes it clear that smoking must be forbidden in the work area. The employee who desires to smoke on his or her own time, during coffee breaks and lunch hours, should have a reasonably accessible area to smoke. Such a rule imposes no hardship upon the telephone company.

The company already has in effect a rule that cigarettes are not to be smoked around telephone equipment. The rationale behind the rule is that the machines are extremely sensitive and can be damaged by the smoke. Human beings are also very sensitive and can be damaged by cigarette smoke. Unlike a piece of machinery, the damage to a human is all too often irreparable. If a circuit or wiring goes bad, the company can install a replacement part. It is not so simple in the case of a human lung, eye, or heart. The parts are hard to come by, if indeed they can be found at all. A company that has demonstrated such concern for its mechanical components should have at least as much concern for its human beings.—Gruccio, J.

—New Jersey Superior Court, Shimp v. New Jersey Bell Telephone Co., 12/20/76. Released for publication 12/31/76.

45 U.S.L.W. 2354, 2/1/77

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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CALL
ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1980 Annual Meeting of the House of Delegates will be held at the Hartford Hilton Hotel, Hartford, commencing at 8:30 A.M. on Wednesday, April 30.

Edward A. Kamens, M.D., President
Joseph S. Sadowski, M.D., Speaker of the House
Louis C. Backhus, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member of The Society, in compliance with the following provisions:

a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.

b. Component county associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.

c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.

d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

PROPOSED AMENDMENT TO THE BYLAWS

The following proposed amendment to the Bylaws was presented to the House of Delegates on November 15, 1979 and was tabled for consideration and action at the next regular meeting of the House of Delegates.

In accordance with the Bylaws, this amendment will be published in *Connecticut Medicine* "on one or more occasions prior to the next meeting . . . at which meeting the amendment shall be taken off the table and acted upon by the House of Delegates."

QUORUM — HOUSE OF DELEGATES
PURPOSE

To reduce the size of the quorum for House of Delegates meeting.

PROPOSED AMENDMENT
ARTICLE V — HOUSE OF DELEGATES

Section 11. Quorum

A quorum at any meeting of the House of Delegates shall consist of a majority of the sum of the number of delegates eligible to vote in the House.

PRESENT BYLAW

A quorum at any meeting of the House of Delegates shall consist of a majority of the sum of the number of delegates to which all component associations are entitled in accordance with Section 4 of Article V of the Bylaws plus the number of members of the Council eligible to vote in the Council.

Current Experiences with the Management of Paraesophageal Hernias

JAMES T. SAYRE, M.D. AND JOHN P. WELCH, M.D.

ABSTRACT—A series of twenty-five patients with paraesophageal hernias were reviewed retrospectively. Most patients were elderly females with significant symptoms. Of ten individuals treated medically, four developed significant complications of the hernia and one died of a perforated stomach within an incarcerated hernia. All surgical patients survived operation and 20% of this group were operated upon within forty-eight hours of admission. None of the surgical group had documented recurrence during the period of follow-up. We favor elective surgical treatment of all symptomatic patients their medical condition permitting.

Paraesophageal hernias are uncommon, comprising 0.7 to 10% of all hiatal hernias.[1-4] The frequency of serious or fatal complications of these hernias has gone largely unrecognized in the literature. Even today their potential dangers are not considered by many practicing physicians. This review of our experience with paraesophageal hernias was done to assess the potential risks and outcome of both medical and surgical treatment.

Clinical Experience

The medical records of the Hartford Hospital were examined retrospectively from 1963 to 1979, and the records of the University of Connecticut Health Center were examined from 1977 through 1979. A total of 25 paraesophageal hernias were identified, five of which were "mixed", i.e. contained elements of both sliding and paraesophageal hiatus hernias. Twenty-two of the patients were greater than 60 years of age, and females predominated in more than a 3:1 ratio. Two asymptomatic patients were found to have paraesophageal hernias after retrocardiac air-fluid levels were identified on routine x-rays of the chest. (Figures 1 and 2). The remaining patients had complaints which could be directly related to the presence of a diaphragmatic hernia. The most frequent symptoms included abdominal pain in nine patients (36%), chest pain in six (24%), heartburn in three (12%), and vomiting in four (16%).

Ten patients were managed medically for reasons such as advanced age, mild complaints, or a total lack of symptoms. (Table I). Of two asymptomatic patients, one died of a cerebrovascular accident in a hospitalization for same, and another was living and well seven years later at age 87. An 84-year-old patient with a guaiac-positive stool noted on routine examination had no complaints related to the chest, and was found during the course of contrast studies to have transverse colon, small bowel, and most of the stomach entrapped in a large paraesophageal hiatus hernia. (Figure 3). He remained well under two years' observation. A 38-year-old patient followed for three years with minimal vague epigastric complaints opted to forego surgical treatment of a small paraesophageal hernia. One patient had a gastric ulcer, which healed with medical therapy alone. An elderly individual who was not a candidate for surgery, responded well to medical treatment of pneumonitis and mild abdominal pain. She was subsequently lost to follow-up. A 78-year-old male who had undergone two previous hiatus hernia repairs and had complained of heartburn and fullness after meals, was stable during a year's observation. Three patients in this group appeared to have acute symptoms of gastric volvulus, with distention and obstruction of the stomach. A 67-year-old female with acute chest pain superimposed on chronic symptoms of

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Reprint requests to: 85 Jefferson St., Hartford, CT 06106 (Dr. Welch).

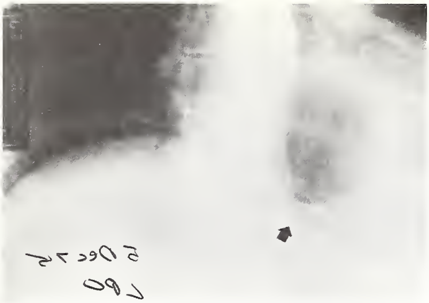

Figure 1
P-A Chest roentgenogram and barium swallow. Note radiolucent area within cardiac silhouette.

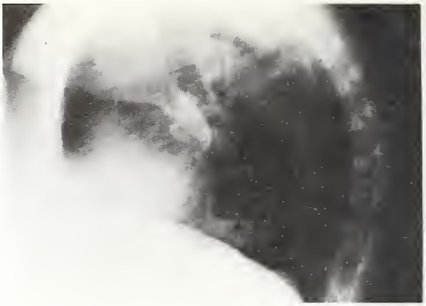

Figure 2
Lateral chest roentgenogram showing retrocardiac air-fluid level within intrathoracic stomach.

heartburn and wheezing improved rapidly with nasogastric decompression, and had no further exacerbations over a 4-year period on antacid therapy. An 87-year-old female was also successfully treated with nasogastric decompression and antacids, but was lost to follow-up. One patient, who died in the Coronary Care Unit, was found to have a strangulated paraesophageal hernia with perforation as the cause of death (Case Report II).

Fifteen patients were treated surgically, usually with closure of the defect and some form of gastropexy or fundoplication. Six patients were operated upon within 48 hours of admission (Table II). All six patients complained of chest or abdominal pain and were treated initially with insertion of a nasogastric tube, with some relief of pain (Case II). One patient had hematemesis caused by a large gastric ulcer in the incarcerated portion of the stomach (Figure 4). A patient with a mixed hernia, who had been symptomatic for five years, vomited vigorously on the day prior to admission and was found at operation to have a Mallory-Weiss tear.

Nine patients with symptoms generally of a milder, less acute nature, were treated with elective operation (Table III). Symptoms ranged over periods from weeks to years, and were characterized by heartburn, anemia, or mild chest and epigastric pain. One patient had a gastric ulcer and another, who had been hospitalized for a myocardial infarction precipitated by massive gastrointestinal bleeding from the incarcerated segment of the paraesophageal hernia, later tolerated an elective surgical approach without complication. None of the patients in this series died as a result of operation. All surgical patients have been followed for at least one year, and none have been reoperated upon for recurrent paraesophageal hernias.

Case Report I

A 69-year-old female with a five year history of a "large" hiatal hernia entered the hospital on 11/25/77 complaining of epigastric pain and vomiting. Acute symptoms had begun shortly after she had completed a large Thanksgiving dinner. Ingestion of small meals had been associated with some indigestion and eructations. She had been hospitalized one year previously with an acute episode similar to the present one, with resolution of symptoms with medical treatment alone.

She appeared flushed, nauseated and dehydrated with a blood pressure of 150/88, pulse 96, and temperature of 100 degrees per rectum. The chest was clear to auscultation. The abdomen was obese

Table I
MEDICALLY-TREATED GROUP

Age/Sex		*Type*	*Clinical Presentation*	*Duration of Symptoms*	*Management*	*Complications***
87	F	PE*	Chest Pain; SOB	Hours	N-G Tube	Pneumonia
84	M	PE	Guaiac + Stools	Unknown	Antacids	None
80	F	PE	Asymptomatic	—	Observation	None
78	M	Mixed	Heartburn, Fullness	Unknown	Antacids	None
74	F	PE	Abdominal Pain	Unknown	Observation	Pneumonia
70	F	PE	Abdominal Pain	24 Hours	N-G Tube	Died—Gastric Perforation
67	F	PE	Chest Pain, Asthma	24 Hours	Antacids	None
66	F	PE	Asymptomatic	—	None	None
51	M	PE	Abdominal Pain	Weeks	Antacids	Ulcer
38	F	PE	Fullness	3 Years	None	None

* Paraesophageal
** Complications directly attributable to the hiatus hernia

Table II

SURGICALLY-TREATED GROUP—EARLY OPERATION

Age/Sex	Type	*Duration Of Clinical Presentation*	*Symptoms*	*Operation**	*Postoperative Complications*
81 F	PE**	Melena	4 Days	Ulcer Plication	
		Abdominal Pain	1 Day	Gastrostomy Gastropexy	Pneumonia
74 F	PE	Dysphagia			
		Epigastric Pain	Hours	Anterior Gastropexy	None
72 F	PE	Epigastric Pain	8 Years	Posterior Gastropexy	None
		Nausea, Vomiting	1 Day		
70 M	PE	Chest Pains	Hours	Nissen Fundoplication	None
70 F	Mixed	Heartburn	5 Years	Posterior Gastropexy	None
		Postcibal Vomiting	2 Years		
		Violent Wretching (Mallory-Weiss)	1 Day		
47 M	PE	Chest Pains	3 Days	Posterior Gastropexy	None
		Bloating, Vomiting Asthma	2 Months	Modified Nissen, Gastrostomy	

* All patients had diaphragmatic defect closure
** Paraesophageal Hernia

but not distended. Mild periumbilical tenderness was present without abdominal masses or rebound tenderness and the bowel sounds were normal. The stool was negative for occult blood.

Insertion of a nasogastric tube relieved the abdominal distress. The hematocrit was 49 percent, the white blood cell count 13,800, with 88 neutrophils and 4 bands, amylase 12, sodium 148, potassium 3.3, chloride 111, CO_2 content 26, total bilirubin 0.6, BUN 21. Chest films demonstrated a large hiatal hernia in the right hemithorax, with a prominent air-fluid level. A barium swallow revealed that virtually the entire stomach was above the diaphragm. Complete obstruction was present in the region of the distal antrum. Gastroscopic examination confirmed the radiological findings, and no gastric ulceration or necrosis was seen. The gastroesophageal junction appeared to be approximately 35 cm below the incisors. Repeat upper gastrointestinal series after 24 hours of decompression demonstrated complete resolution of gastric outflow obstruction, and bilious drainage was seen coming from the nasogastric tube.

Elective operation was performed on the third hospital day. The intrathoracic stomach was reduced successfully from an abdominal approach, but the boundaries of the defect were not closed due to limitation of exposure. An anterior gastropexy and gastrostomy were also performed. The postoperative course was generally smooth except for bronchopneumonia responding to antibiotics and chest physiotherapy. Oral fluids were begun one week postoperatively when active peristalsis reappeared. A repeat upper gastrointestinal series demonstrated an open pylorus, edema of the body and antrum of the stomach and no esophageal reflux.

Comment: This patient was treated in a semi-elective fashion after the distended stomach was successfully decompressed with a nasogastric tube. "Reentry" of the fundus into the abdomen was not demonstrated radiologically, and the obstruction was transitory. In retrospect, the current operation should have been carried out a year previously, since the present episode could have proved fatal.

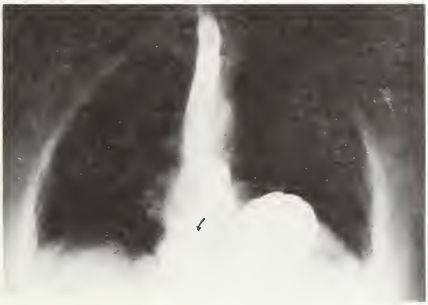

Figure 3
Upper GI series demonstrates "mixed" diaphragmatic hernia, where gastroesophageal junction (arrow) lies just above the diaphragm.

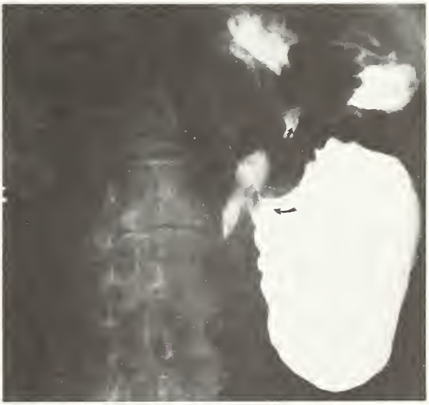

Figure 4
Upper GI Series illustrating huge intrathoracic stomach with ulceration (upper arrow) and normal position of gastroesophageal junction below the diaphragm (lower arrow).

Table III

SURGICALLY-TREATED GROUP—ELECTIVE OPERATION

Age/Sex	*Type*	*Clinical Presentation*	*Duration of Symptoms*	*Operation**	*Postoperative Complications*
72 F	PE**	Belching, Indigestion	Months	Nissen	None
71 F	PE	Heartburn, Dysphagia	2 Years	Fundoplication	None
71 F	PE	Epigastric Pain	2 Years	Defect Closure Only	Pneumonia
69 F	PE	Chest Pain, Regurgitation	1 Year	Anterior Gastropexy	None
69 F	Mixed	Chest Pain, Regurgitation	3 Months	Nissen	None
69 F	Mixed	Epigastric Pain, Vomiting	1 Week	Posterior Gastropexy	Wound Hematoma
64 F	PE	Anorexia, Abdominal Pain	2 Weeks	Gastrostomy, Excision Gastric Ulcer	None
62 F	PE	Anemia	4 Months	Anterior Gastropexy	None
51 M	Mixed	Hematemesis	Hours	Nissen	Acute MI

* All patients had closure of diaphragmatic defect

** Paraesophageal

Case Report II

A 70-year-old white female with a six year history of a large hiatal hernia entered the hospital 11/8/76 after a 24 hour history of epigastric and right upper quadrant pain associated with nausea. Five years earlier she had undergone plication of a perforated duodenal ulcer. She had been hospitalized with epigastric pain, "gastric ileus, and hyperamylasemia," a year earlier. Her symptoms had resolved rapidly after nasogastric intubation, with drainage of 1350 mls. of gastric contents. She had done well on a medical ulcer regimen until the present episode. She appeared flushed with cool dry skin. The blood pressure was 70 mm.Hg. palpable, pulse 100, temperature 98°F rectally. The chest was clear to auscultation. The abdomen was soft, nondistended, and tender in the upper quadrants. No bowel sounds were present. The stool was negative for occult blood.

Admission laboratory studies included a hematocrit of 46%, white blood cell count 3,000 with 56 band forms and 13 neutrophils. The serum sodium was 135, potassium 5.6, chloride 108, total CO_2 19, BUN 42 and amylase 22 (normal less than 13). A chest x-ray showed a huge hiatus hernia. The patient's symptoms were relieved by nasogastric intubation, and her cardiovascular status improved with aggressive fluid replacement. The nasogastric tube was removed on the fifth hospital day. An upper gastrointestinal series demonstrated a large gastric ulcer in the intrathoracic stomach. Volvulus was also present but the stomach emptied. The following day she developed the sudden onset of diaphoresis, tachypnea, and severe epigastric and low substernal pain. She followed a relentless downhill course thereafter, and died 24 hours later. At post mortem examination, there was a large paraesophageal hernia containing stomach, colon and omentum; diffuse gastric mucosal erosions; a 3 cm. gastric ulcer with perforation; and extravasation of gastric contents.

Comment: This patient demonstrated two of the catastrophic complications of paraesophageal herniation of the stomach: acute volvulus with obstruction, and gastric perforation. The danger of expectant medical therapy is emphasized.

Comments

A hiatal hermia is defined as an abnormal protrusion of an anatomic structure through the esophageal hiatus of the diaphragm. The two principal types of diaphragmatic hernia include the sliding type (type I) and the paraesophageal variety (type II).[5] About 2% of radiologically demonstrated diaphragmatic hernias are of the paraesophageal type, compared to 3 - 11% of all hiatus hernias operated upon.[6] With a pure paraesophageal hernia, the gastroesophageal junction remains in its normal position below the diaphragm, held in place by an intact phreno-esophageal ligament. The hernia sac is formed from the attenuated anterior and lateral portion of the phreno-esophageal fascia.[2] This is in distinction to a sliding hernia, where the gastroesophageal junction generally precedes the stomach within the herniation into the chest, because of weakening of the posterior phreno-esophageal ligament. Some diaphragmatic hernias are "mixed" or "combined," i.e., the gastro-esophageal junction may move a small distance above the diaphragm accompanying a substantial visceral herniation into a sac lateral and superior to the gastro-esophageal junction.

Paraesophageal hernias occur through the true esophageal hiatus anterior and adjacent to the esophagus into the right and left pleural spaces, rather than through a defect separate from the hiatus.[2] The fundus of the stomach usually herniates first and the stomach may roll into an upside-down position, with the greater curvature upward. It is unkown whether the paraesophageal hernias are congenital[2,7] or acquired. Such herniations have followed operations such as truncal vagotomy.[8] The rare occurrence of these hernias before middle age, however, suggests that they are acquired.[4]

The symptomatology of patients with paraesophageal hernias is variable. Many individuals are asymptomatic or have minimal complaints. The stomach maintains its intrathoracic position providing insignificant interference with normal peristalsis or compromise of function of thoracic organs. Such hernias are discovered in routine chest roentgenograms or contrast studies obtained for unrelated reasons. At other times clusters of symptoms can be identified. Symptoms result when the stomach incarcerates and subsequently obstructs partially or fully, ulcerates, perforates, or decompresses. Pain from gastric distention is the most frequent presenting symptom. Gastric distention may be produced in several ways. As the fundus rolls into the chest, compromise of the gastric lumen sometimes occurs at the diaphragm. With simple herniation of the fundus, fullness or bloating may be seen, particularly following ingestion of a large meal. Relief comes as food is gradually passed from the thoracic stomach by peristalsis or by spontaneous reduction of the hernia. Spontaneous reduction may account for a common symptom complex of several patients in this series, characterized by postprandial bloating and a sense of "something moving inside" relieved by a single episode of regurgitation. As the distended fundus returns into the abdomen the loss of the gastroesophageal angle may momentarily render the lower sphincter incompetent. This may explain in part the heartburn noted by 20% of our patients.

Complete obstruction of the stomach occurs in two ways.[9 10] Volvulus may occur when herniation is large and follow rotation of the stomach on the mesentery (mesenteroaxial) or rotation on its long axis (organoaxial). Complete gastric outlet obstruction may also occur when the intrathoracic portion of the stomach becomes large, the fundus alone reenters the abdomen[3 11] and the distal stomach is compressed at the hiatus.

Complete obstruction produces Borchardt's classic triad, that includes 1) epigastric pain, 2) ineffectual vomiting, and 3) inability to pass a nasogastric tube. The epigastric pain is characteristically severe and constant. This pain is often confused with that of myocardial infarction or that of other intra-abdominal emergencies. The markedly distended intrathoracic stomach can produce hyperresonance of the left chest just as a tension pneumothorax in a desperately ill patient.[12] Failure to recognize the condition may be catastrophic if the obstruction remains complete, and progressive distention of the stomach occurs. Ultimately, the vascular supply of the stomach becomes compromised.[13 14] The stomach wall weakens and eventually perforates. Shock and death nearly always result.

Gastrointestinal bleeding was the presenting complaint in three patients (12%) in this series. Ulcers were found in up to 30% of incarcerated stomachs in some reports.[2 4] The mechanism of the gastrointestinal bleeding and ulcer formation may include excess acid production secondary to gastric distention or interference with gastric emptying and periodic interference with circulatory perfusion.[15 16] A large intrathoracic stomach occasionally comprises the function of adjacent organs. Pneumonia was seen in three of our patients and three other patients suffered from asthmatic attacks. Atelectasis was common. One patient reported exacerbation of wheezing by large meals. It is unclear whether the distended stomach alters the configuration of the bronchial tree or whether increased vagal tone resulting from gastric distention stimulates hyperactive bronchial smooth muscle as seen in asthma. Increased vagal tone also manifests itself by bradycardia in some patients.[17] Although undocumented, the distended intrathoracic stomach may also compromise myocardial function by direct compression of the atrium or vena cava, or by shifting of the mediastinum.

The diagnosis of paraesophageal hernia is usually made by clinical suspicion and characteristic chest x-ray findings. A double air-fluid level behind the heart "(diamond shadow)" represents volvulus of the stomach with dilatation of the proximal and distal portions of the organ.[4] More common is a single retrocardiac air-fluid level. A similar x-ray picture may be produced by epiphrenic diverticula,[18] Bochdalek hernia,[19] post-traumatic diaphragmatic hernia,[20 21] eventration,[22] intrathoracic cysts, loculated pneumothorax, empyema, pneumatocele, pulmonary sequestration,[23] lung abscess,[24] carcinoma of the lung or a large sliding hiatal hernia. The differential diagnosis can usually be made from clinical presentation and then confirmed by barium swallow.[25] The small bowel or colon may be seen within the herniation with contrast studies.[26] Eventration can best be defined with the use of pneumoperitoneum.[22] Endoscopy is occasionally useful if the findings in upper GI x-rays are unclear.[4 27] Characteristically, no reflux esophagitis or incompetence of the lower esophageal sphincter accompanies a paraesophageal hernia (Figure 5).

Surgical Therapy

Paraesophageal hernias should be repaired in all patients including asymptomatic ones, unless there are obvious medical contraindications. In the case of volvulus of the stomach, emergency operation is es-

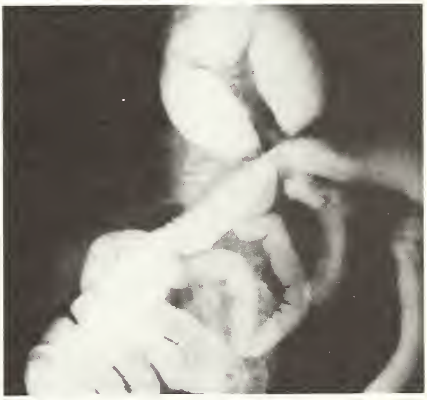

Figure 5
Barium enema view of the transverse colon lying in paraesophageal hernia sac above the diaphragm.

sential unless the stomach can be promptly decompressed with a nasogastric tube. Anesthetic management may be difficult. Compression of the heart and lungs by the distended stomach causes dyspnea, rapid respirations, atelectasis, tachycardia, and decreasing venous return. Spontaneous breathing is preferred to positive pressure breathing, since the latter may further decrease venous return and cause death. Aspiration of stomach contents is prevented by the inflated cuff of the endotracheal tube during the handling of the distended viscus.[28] Once the stomach is deflated, muscle relaxation aids in replacing the viscera into the abdomen.

An abdominal approach is satisfactory in most cases through an upper midline incision, especially if intraabdominal pathology such as cholelithiasis or peptic ulcer disease is suspected. After the left triangular ligament of the liver is divided, the region of the gastroesophageal junction is exposed. Care is taken to avoid excessive dissection of the gastroesophageal junction since the phrenoesophageal ligament and the competence of the valve mechanism may be disturbed.[29] The stomach is then pulled down into the abdomen with gentle traction (see Figure 6). Needle aspiration may facilitate reduction of the stomach in the case of incarceration or volvulus.[29,30,31] Care must be taken in releasing the incarcerated stomach by incision of the rims of the hiatus; perforation of the stomach has been reported with this maneuver.[31] The hernia sac is then dissected free of surrounding structures and is removed as completely as possible from the posterior mediastinum.

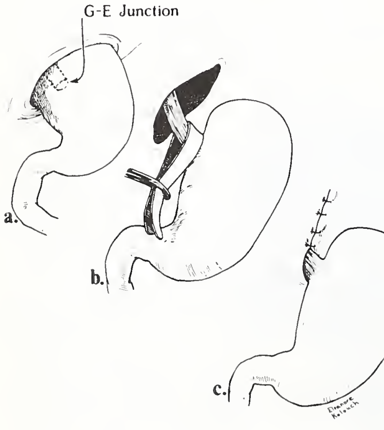

Figure 6
Operative steps in paraesophageal hernia repair.
a.) Gastroesophageal junction and portion of the stomach lie within the abdomen.
b.) Mobilization of the stomach from the posterior mediastinum.
c.) Closure of hiatus following excision of hernia sac.

Once the sac has been excised it is possible to place heavy nonabsorbable sutures in strong tissues of the crura anterior to the esophagus. At the completion of the operation the hiatus should admit one finger adjacent to the esophagus. If desired a gastrostomy can be added to provide drainage of the edematous, chronically incarcerated stomach, and to lessen the opportunity of recurrent herniation of the stomach into the chest. Rather slow resumption of gastric peristalsis is common once the stomach has been incarcerated.

In the usual case, a further formal hiatus hernia repair is unnecessary. However, if the posterior esophageal ligament has been weakened or if some gastroesophageal reflux is present in the case of a mixed hernia, a Nissen fundoplication or a Hill posterior gastropexy utilizing the median arcuate ligament is preferred. A simple gastric ulcer need not be resected. Except in the case of perforation or active bleeding of the ulcer, a local excision usually suffices. Gangrenous portions of the stomach or of other viscera must be resected.

Depending on the preference of the surgeon, a thoracic approach may also be used. Dissection in the very obese patient is easier via a transthoracic approach through the left seventh or eighth interspace. The exposure through the chest may be best in individuals with dense adhesions between the hernia sac and the mediastinum. In elderly individuals, the morbidity of a thoracic approach however may be greater than that of an abdominal approach. Furthermore, it is sometimes difficult to expose a hernia extending into the right chest through a left thoracotomy incision. At times a combined thoraco-abdominal incision is preferable, when the stomach is incarcerated and the hernia is of considerable size. Once perforation has occurred into the chest, the posterior mediastinum must be opened widely and well-drained.[32]

Except in the case of gastric strangulation or perforation the operative mortality should be low. If the patient survives the procedure symptomatic recurrence is not common,[2,4,33] although radiological recurrence of paraesophageal hernias was found in 33% in one series.[1] With long-term follow-up, the recurrence rate tends to increase gradually even ten years following the procedure.[1]

Which patients with paraesophageal hernias should be operated upon? There was only one death amongst our group of patients during the period of observation, and categorical answers to such a question cannot be made. We would agree, however, that any symptomatic individual with a paraesophageal hernia is in danger of life-threatening complications, and should be an operative candidate unless medical contra-indications are great. It is impossible to predict which patients will develop severe complications, and prospective studies are virtually non-existent in the literature. Skinner and colleagues began a prospective study of twenty-one patients treated medically, but six patients died of severe complications such as strangulation, perforation, exsanguinating hemorrhage, or acute dilatation of the stomach. The remaining patients were operated upon and the study was abandoned.[34]

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Myocardial Contusion: A Review of a Case of Transient Bifascicular Block

HARRY J. SARANCHAK, M.D. AND KENNETH T. JOHNSON, M.D.

Violent accidents are responsible for the majority of deaths under the age of forty.[1] It is probable from medical examiner reports that cardiac trauma is the most common unsuspected injury responsible for death in fatally injured victims.[2]

The pathology involved in blunt cardiac trauma is usually classified into four main categories (Table 1). We present four cases of myocardial contusion illustrating some of its sequellae including one case presenting with the unusual complication of transient bifascicular heart block.

Table 1

CLASSIFICATION OF CARDIAC LESIONS IN NONPENETRATING CHEST TRAUMA

- I. Myocardium
  - A. Contusion*
  - B. Rupture
  - C. Septal Perforation
  - D. Late Aneurysm Formation
- II Valvular Dysfunction and Rupture
- III. Coronary Artery
  - A. Contusion and Thrombosis
  - B. Laceration
  - C. Late Fistula Formation
- IV. Pericardium
  - A. Disruption
  - B. Hemopericardium and Tamponade
  - C. Early and Late Traumatic Pericarditis

Case #1

A 17-year-old white male was admitted after being struck in the anterior lower chest by a helmeted head while playing football. He complained of severe left-sided chest pain. EKG (Figure 1) demonstrated left axis shift and a sinus arrhythmia with episodes of sinus arrest. After a few days of observation the EKG returned to normal and the chest pain subsided.

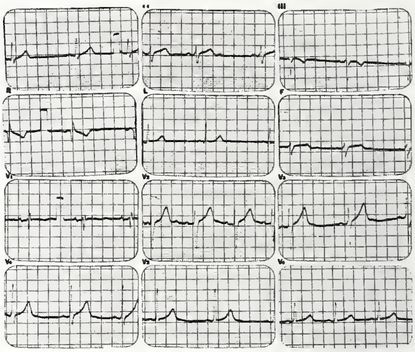

Figure 1

Case #2

A 26-year-old white male was admitted with multiple injuries following an automobile accident, including severe head injuries, facial fractures, and a dislocated right hip. He also received an obvious chest injury with right-sided subcutaneous emphysema. Chest x-ray revealed pneumomediastinum. EKG upon admission showed an idioventricular rhythm (Figure 2), but the next morning returned to normal (Figure 3). Total CPK was 6230 with an increased MB fraction. The following day this was borderline and was absent on the third day when he died from his head injuries. Autopsy was consistent with myocardial contusion and the pathology appears in Figures 4, 5, and 6.

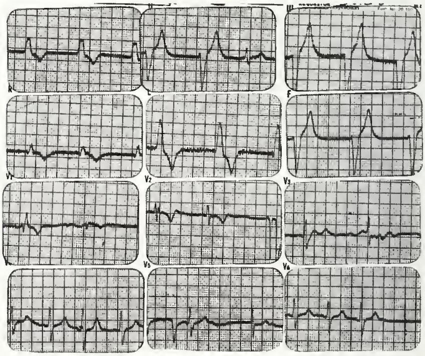

Figure 2

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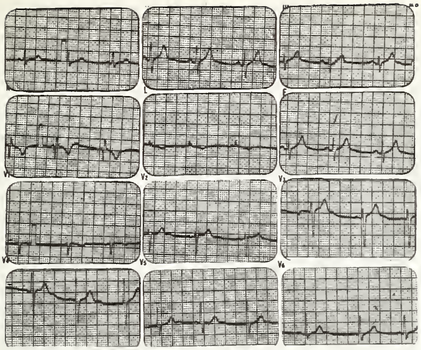

Figure 3

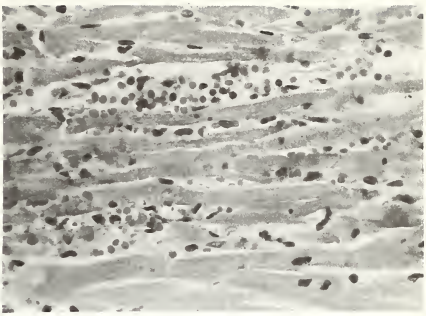

Figure 5

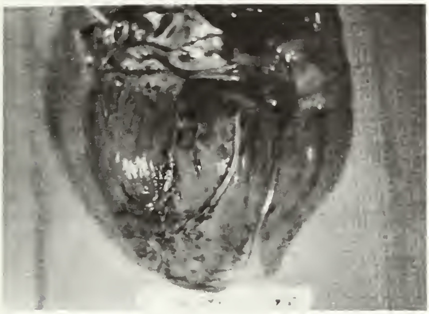

Figure 4

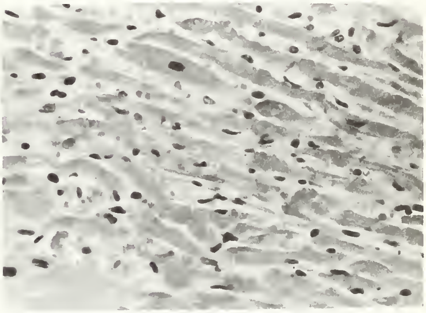

Figure 6

Case #3

A 33-year-old white male with a previously documented normal ECG on routine physical examination was involved in an automobile accident with a trailer truck on his way to work. Besides a compound fracture of his right forearm and superficial lacerations of his face and both legs, he had an obvious steering wheel injury with distortion of his left hemi-thorax caused by injury to the costal cartilages. Upon presenting to the Emergency Room his systolic blood pressure was 50, however, his pulse was only 50. After oxygen and minimal intravenous fluids were administered, his blood pressure quickly increased. A chest x-ray revealed some mediastinal widening but an aortogram proved to be normal. SGOT, LDH, and CPK rose dramatically, and the CPK to over 2,000, however, the myocardial fraction of the LDH and isoenzymes of CPK were only minimally elevated. EKG upon admission showed sinus bradycardia, SA block with junctional escapes, ST changes consistent with ischemia, and especially right bundle branch block and left posterior hemiblock, with a negative vector in lead 1 (Figure 7). Later that evening the patient had episodes of total sinus block with junctional escapes. At that time a pacemaker was considered but because of an adequate junctional compensatory rhythm it was decided to reserve this. Over the next few days the EKG returned to normal with only some ST segment elevation and two weeks after the accident the EKG was normal (Figure 8).

Case #4

A 19-year-old white male was admitted to another hospital with a severe steering wheel injury and a fractured sternum. Chest x-ray was normal except for a question of slight widening of the mediastinum. EKG revealed severe ST segment elevation across the precordial leads and occasional premature ventricular contractions consistent with a myocardial contusion (Figure 9). Aortogram was normal. Pericardiocentesis was performed because of a low systolic blood pressure and high central venous pressure causing concern about the possibility of tamponade. This was negative. He did well with only fluid replacement and repeat EKG's over the next few days showed decrease in the ST elevation. He was discharged rather early on the fifth day. Three weeks later he was admitted to our hospital with a fever of 102 and diffuse anterior chest pain aggravated by deep breathing. A pericardial rub was heard along the left sternal border. WBC count was 8,300, sedimentation rate was 50. ASO titres and a LE prep were negative. Enzymes were normal. Chest x-ray revealed an enlarged heart shadow. An EKG was consistent with pericarditis with marked ST elevations across the anterior leads. A pericardiocentesis produced 150 ml. of sanguinous non-clotting fluid. Cultures proved to be negative. Following this he improved but over the next few days his symptoms returned. He was therefore started on prednisone 60 mgm/day and quickly tapered. Further EKG's over this period continued to be consistent with acute pericarditis but

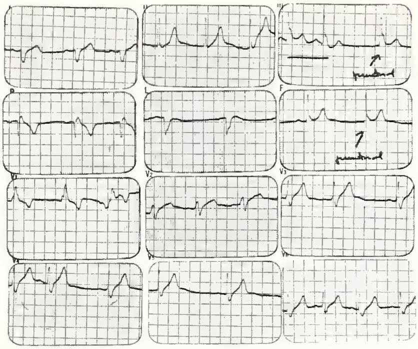

Figure 7

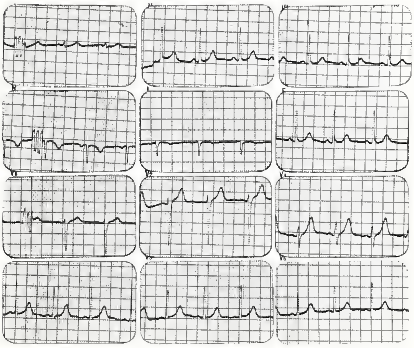

Figure 8

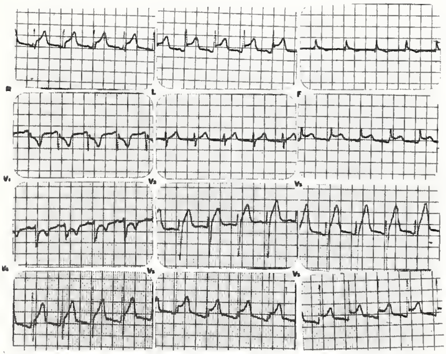

Figure 9

showed obvious improvement. He was discharged afebrile and asymptomatic on 30 mgm/day of prednisone. Attempts at stopping prednisone have met with recurrence of symptoms.

Discussion

The first report of a myocardial contusion dates back to 1676 when Orloff Borch first reported the death of an 8-year-old boy in London thought to be due to a myocardial contusion.[3] In 1859 Schnabel[4] reported the first autopsy findings consistent with myocardial contusion. However, Kahn and Kahn[5] and especially Bright and Beck[6] have contributed most of our modern knowledge of myocardial contusion with their laboratory and clinical correlations.

There are three primary mechanisms thought responsible for most myocardial contusions. The first is direct compression of the heart between the sternum and vertebrae, the typical steering wheel injury. An interesting aspect of this mechanism is that injuries without rib fractures may be very subtle in that, given an equal amount of force, Bright described greater damage when ribs are not broken, implying that rib fracture has a protective influence by absorbing and dissipating energy forces. The second known mechanism is sudden acceleration or decelleration thrusting the heart against the sternum or vertebrae. Thirdly, myocardial contusion can actually occur without chest trauma. To explain this, Stapp[7] and Lasky[8] have described the hydraulic effect by which severe fluid compression following trauma to the abdomen or lower extremities can be transmitted up the inferior vena cava injuring the heart.

The pathology of myocardial contusion resembles infarction but there are subtle differences which can differentiate the two. Acutely the heart shows petechiae and ecchymoses in the subendocardial and subepicardial tissue (Figure 4) but there may be a large area of transmural hemorrhage under this. Microscopically at 24 hours there is interstitial hemorrhage (Figures 5 and 6). The transition from normal to abnormal tissue is quite abrupt unlike the slow transition in myocardial infarction. Later leukocytes invade with eventual healing by scar exactly like myocardial infarction which explains the similarities of the late complications of both contusion and infarction. However, the pathology is difficult to produce experimentally without killing the animal and significant injury can present with arrhythmias without pathologic change at autopsy.

Seventy percent of patients with myocardial contusion present with chest pain in the anterior chest similar to ischemia and often with radiation to the left shoulder and arm. Actually, most patients complain of two types of pain; one due to chest wall injury and the other, anginal in quality and neither pain responds to coronary vasodilators.

Immediately following the accident the electrocardiogram may be normal but one third of the patients develop RS-T complex changes and/or T wave changes similar to myocardial ischemia within 24 to 48 hours. These changes usually disappear within a month and if they do not, one must suspect either pre-existing coronary disease or serious necrosis and scarring. In a study of myocardial contusion by Dolera,[9] 5 had slight ST changes, either elevation or depression; 4 had severe changes; and 14 had flattening of the T waves.

Arrhythmias are one of the most serious problems posed by myocardial contusion and the cause of most sudden deaths. Almost every type of arrhythmia has been reported. Arrhythmias usually originate from the injured myocardium becoming an unstable electrical focus. However, some arrhythmias such as sinus tachycardia or bradycardis may result from sympathetic or vagal stimulation.

In the human heart the bundle of His divides into its three main fascicles, the right bundle branch, the left anterior, superior and the left posterior, inferior bundle branches. It is therefore not surprising that a small lesion in the upper interventricular septum can give rise to blocks of any one or more of these fascicles. A transient block after trauma would represent edema or hemorrhage while a permanent block implies actual interruption of the conduction pathways.

The English literature records three patients with bifascicular block following closed chest trauma. Two episodes of right bundle branch block and left posterior hemi-block are documented by Parmly[10] in 1958, however, both were associated with extensive injury and septal necrosis with valvular dysfunction documented at operation or autopsy. One episode of right transient bundle branch block and left anterior hemiblock is documented by Goza[11] in 1972 but his case was associated with shock and renal failure with hyperkalemia at the time of the block, and hyperkalemia can cause transient block in itself.

We believe that Case #3 represents the first reported case of transient bifasicular block to be documented following an entirely non-complicated myocardial contusion.

SGOT, LDH, and CPK will usually rise in the presence of a myocardial contusion but this is nonspecific and has been found to occur in other injuries. Isoenzymes of CPK have not been studied but may show some promise.

Jones[12] in 1975 reported the complications associated with 18 well documented myocardial contusions. Early in the course six had arrhythmias, five had congestive failure, and two had heart block. Within two weeks of injury there were four cardiac tamponades. There was one case of late constrictive pericarditis.

Late traumatic pericarditis may follow a myocardial contusion. Case #4 supports the hypothesis that this syndrome like post-myocardial infarction pericarditis may be an altered immune response to damaged myocardial tissue.

Some further sophisticated studies have been employed recently to aid in the diagnosis of myocardial contusion. Go and Chester[13] have shown in both dogs and humans the increased uptake of technitium stannous polyphosphate in the first two to three hours following myocardial contusion. It is thought to be sequestered in injured mitochondria. Ware and Morten[14] have shown a scan to be effective in dogs based on the decreased uptake of technitium labelled albumin microspheres.

The therapy of myocardial contusion is expectant and parallels that of myocardial infarction. Most authors note the importance of bedrest with a slow, graded return to normal activity. An appropriate correction of hypovolemia and hypoxia from associated injuries which may decrease flow to an already damaged myocardium is imperative. However, there must be an avoidance of fluid overload in the face of a compromised myocardial reserve with the early use of central venous pressure monitoring and more appropriately Swan-Gantz catheters. Impedance plethysmography has been used to estimate decreases in cardiac output and this may be the first change which can be measured in all myocardial contusion patients. Prolonged monitoring is undertaken with treatment of cardiac arrhythmias as they present. Temporary pacing may occasionally be necessary to treat heart block. Congestive heart failure is treated with diuretics and digitalis preparations, however, digitalis preparations should be avoided unless overt failure is present because they can potentiate arrhythmias in an already excitable myocardium. Anticoagulation is usually avoided. This has the theoretical disadvantage of increasing hemorrhage in the myocardium, however, the few times it has been employed it has not seemed to make any practical difference.

Coronary vasodialators have shown no effect on the pain associated with myocardial contusion and may decrease blood pressure in the trauma patients. Complications must be anticipated with a high index of suspicion for tamponade, when hypotension occurs in the first few days. However, tamponade has been reported up to three months following injury. Aneurysm formation, and late constrictive pericarditis have been reported and life threatening complications, thought due to contusion, have occurred up to one year after the injury.

Of medicolegal importance is the sometimes great difficulty in differentiating the effects of cardiac trauma from those of pre-existing coronary artery disease. Here the importance of a good documented history, physical, serial EKG's and occasionally even angiography to rule out pre-existing disease is apparent.

Myocardial contusion is more frequent than realized and, as in all trauma, a high index of suspicion, and the tenacity to continue to monitor for extended periods of time, can save lives.

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The Ubiquitous Phlebolith

ROBERT M. LOWMAN, M.D.

Sweet are the uses of adversity;
Which like the toad, ugly and venomous,
Wears yet a precious jewel in his head;
And this our life, exempt from public haunt
Finds tongues in trees, books in the running brooks,
Sermons in stones, and good in everything.

—As You Like It: Act II, Scene I, Line 12: William Shakespeare

The unpretentious little phlebolith, for the most part relegated to a position of inconsequence, is such a ubiquitous roentgen finding that it evokes no specific diagnostic response especially when it is demonstrated in the spleen or pelvic area. On the other hand, the presence of one or more phleboliths in an unusual location in the abdomen or in a soft tissue mass may often be of valuable diagnostic aid. Their presence in the abdomen may be especially significant if the patient is being evaluated for gastric or intestinal bleeding. The combination of phleboliths and an abdominal mass is rarely recognized, although it has been stressed by various authors because phleboliths in association with abdominal masses are such rare entities. Recognition of phleboliths in the miasma and confusing morass of gas and bowel shadows is also difficult. Thus, the presence of phleboliths contained in an abdominal vascular mass, while stressed as a diagnostic aid, can rarely be utilized.

There has been a recent resurgence of interest in pelvic phleboliths concerning the epidemiology and etiology of these opacities. The radiologist can envisage the pelvic phleboliths fixed in their spatial distribution and liken them to the small rounded orbs representing the planets as in an ancient celestial map of the heavens. These are recognized as blood clots which become phleboliths on calcification resulting from changes in coagulation tendencies or in fibrinolytic activity or from localized changes involving the vessel wall or indeed a combination of all of these factors. Various authors have suggested that where phleboliths are found, episodes of prior bleeding into the wall of the abnormal vessels may have occurred. These discrete, rounded opacities range in size from one or two

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millimeters to as much as five millimeters in diameter. The heavily calcified phleboliths are radiopaque, while others may show a relatively radiolucent center. Burkitt et al have suggested that fiber-depleted diets may be involved in the pathogenesis if pelvic phleboliths both by their demonstrated effect on intra-abdominal viscera and consequently, upon intravenous pressures and by their postulated role in altering clotting mechanisms.[1] In some cases, the failure to produce alterations in the intravenous pressures of some of the hemangiomas or vascular malformations of the bowel may be one of the reasons why so few phleboliths are seen in the rarely occurring vascular lesions in the abdomen.

On the other hand, varying numbers of phleboliths may be found associated with vascular masses in the extremities and in the abdomen and in cases of the Klippel-Trenaunay snydrome suggesting that a combination of a variety of factors may be present for the formation of phleboliths in this entity. Moreover, phleboliths contained in the extremities are more easily recognized than those which can be found and demonstrated in the abdominal cavity.

As long ago as 1919, Ruggles[2] astutely predicted that phleboliths in the liver and the intestines could be used to identify vascular masses in these organs following the demonstration of rounded opacities in hemangiomatous soft tissue tumors in the extremities. Thirty years later, Hansen[3] in a comprehensive study of hemangiomas of the small intestine, reviewed 23 cases of his own. In his series of cases, the phleboliths were subsequently demonstrated by the pathologist in the postoperative specimen. In the comprehensive review by Gentry et al[4] of the vascular malformations of the gastrointestinal tract it is noteworthy that the presence of phleboliths is not even discussed. Other authors described phleboliths and hemangiomas of the stomach, small and large bowel,[5 6 7 8 9] emphasizing the radiologic value of the recognition of phleboliths as an important diagnostic clue. More recently, the association of diffuse cavernous hemangiomas of the colon in the Klippel-Trenaunay syndrome has been described by Ghahremani et al.[10] In this syndrome of cutaneous hemangiomas, a bone and soft tissue hypertrophy of the lower extremities and congenital varicose veins, phleboliths have been described in the diffuse hemangiomas. Moreover, phleboliths have also been described in the vascular components of Maffucci's syndrome, i.e., hemangiomatosis of the skin and the dyschondroplasia associated with skeletal enchondromatosis.[11] Illustrative of the problem concerning the difficulties of recognizing abdominal phleboliths is a recently encountered case. Barium studies demonstrated an irregular deformity of the proximal descending colon in a 30-year-old healthy male who presented with a history of a sudden massive large bowel hemorrhage. The contrast studies indicated that the lesion at fluoroscopy was soft and altered its configuration with pressure. A small rounded density on the lateral aspect of the lesion was the key to the diagnosis of the vascular mass of the large bowel. This was identified as a phlebolith contained in a large bowel hemangioma which was subsequently confirmed at surgery.

Outside of the gastrointestinal tract, phleboliths may also provide diagnostic signs associated with hemangiomas. An example of such a vascular mass of the mediastinum may be found in Felson's textbook[12] and similar cases have been described by Lessure[13] and Seybold.[14]

More than half a century following Ruggles' original description, Resnick and Oliphant[15] made the same observation in three cases of synovial hemangiomas which were associated with phleboliths.

The recognition of the ubiquitous phlebolith may be of diagnostic value in one other situation. This may be referred to as the wandering phlebolith as described by Steinbach.[16] This author noted that phleboliths may be displaced by pelvic masses and that recognition of this displacement can help in the radiologic diagnosis of masses in the pelvic area. This phenomenon was subsequently utilized by Fenlon and Augustine[17] in a report of three cases of pelvic masses either neoplastic or traumatic in origin.

The preoperative recognition of the cavernous hemangioma of the gastrointestinal tract is most important since these lesions are always curable. The recognition of the associated phleboliths can be an important diagnostic feature, but it must be stressed that it is quite difficult at times to document their presence. This difficulty is most pronounced in rectal hemangiomas since calcific deposits are normally found in the parametrial, bladder and prostatic areas. There is no doubt that the recognition of these tiny densities can be a valuable preoperative diagnostic aid. The pursuit of the ubiquitous and the occasional peripatetic phlebolith in many cases may be difficult, but at times it may produce a significant diagnostic yield. While it is difficult to document their presence in some areas, one should at least be alert to the fact that these changes can occur.

The sentinel phlebolith like Shakespeare's jewel in the toad's head can on occasion be a significant diagnostic aid.

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Micro Determination of Blood Lead: Reliability for Mass Screening of Children

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ABSTRACT—The reliability of a micro blood lead test for screening children in a large scale, city-wide program in New Haven was evaluated. When micro test results were compared with macro test results, after appropriate matching for age, race and date of sample, there was no evidence to indicate any substantial inaccuracies of micro results. It appeared that the micro method was satisfactory for determining the epidemiology of lead absorption and distribution among New Haven children.

Introduction: Public Health Significance of the New Haven Screening Program

Few childhood blood lead screening programs have reached a large enough proportion of the at-risk population of children aged one through six years to provide a reliable basis for descriptive epidemiology of blood lead values in the entire pediatric population of a city. Accurate information is needed as a basis for: a) better understandings of blood lead distributions by age, sex and race; b) correlations of children's blood lead values with environmental lead sources both within and outside of houses; c) correlations of pediatric lead levels with demographic, socioeconomic and seasonal factors and; d) development of preventive strategies that take all the foregoing variables into account.

Background

From July 1974-February 1977, a screening program for childhood lead poisoning was carried out by the Health Department of the City of New Haven. The program has been described elsewhere.[1] During the two and a half years, more than 11,000 blood lead determinations were performed on 8,334 children, in the age group one through six years. These children

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included about 80% of the entire one through six year old population of the City of New Haven during this time period. It was possible to screen this major portion of New Haven children in these highest risk age groups because a simple micro method was available for measurement of the lead content of whole blood.

Effective use of a mass screening method depends not only on its accuracy in the controlled laboratory situation, but also on its applicability to practical field conditions. Therefore, a primary consideration in any analysis of the New Haven data was the reliability of screening methods. This report summarizes: reasons for selection of this micro method as the major indicator of body uptake of lead; and, comparison of macro and micro test results.

Screening programs for childhood lead poisoning have used several methods to estimate either the body burden of lead (indicated by blood lead level), or the degree of effect an excess lead burden may have had on biological processes. Urinary porphyrins and the free erythrocyte porphyrin (FEP) test measure some of lead's biological effects.[2] Although the FEP test is a valuable tool for screening out children who may have lead poisoning, it correlates poorly with blood lead when lead levels are below 30 µg/100 ml. Therefore, it cannot substitute for blood lead in studies of the distribution of blood lead in the total pediatric population.

Blood lead level provides an indication of tissue lead content and total body lead burden. Blood lead makes up approximately 2% of the total body lead pool and is in constant dynamic interchange with lead deposits in the other body tissues.[2] An elevated blood lead level is a reliable indicator of excessive exposure.[3] Fluctuations in blood lead level reflect recent fluctuations in actual lead intake, thereby providing an excellent index of current and recent absorption of lead. The degree of toxicity represented by the blood lead measurement is not always clear: children with identical blood lead values rarely show identical toxicologic responses.[4] Elevated values may be reported as a result of contamination of the sample, therefore a repeat sample should be taken promptly for confirmation. False negatives are likely in children with anemia because blood lead is more than 90% red blood cell bound.[2] All factors considered, the blood lead concentration is a generally accepted diagnostic tool and an essential measurement in suspected cases of lead poisoning. It is the standard test against which all other tests are compared.

For many years, blood lead determinations were difficult, time consuming and expensive. They required several milliliters of venous blood, which made mass screening of pediatric populations impracticable. In the early 1970's, micro methods for blood lead determination were developed and by 1972 a reliable technique had been perfected.[5 6] This permitted the design of a program to screen a major proportion of the population of at-risk children in New Haven, using finger-prick blood samples of 0.25 ml.

Laboratory Reliability

Test methods depended on the laboratory facilities available to health services in New Haven that monitored children for undue lead absorption. The laboratory facilities used in the program were limited to the State Health Department laboratory and Yale-New Haven Hospital. The analytical and quality control methods used by these laboratories were as follows:

1. With the exception of Yale-New Haven Hospital, all medical care providers including the City Department of Health, sent their blood samples to the State Health Department - Laboratory Division in Hartford, Connecticut. The State used the Dithizone method,[7] of analysis for macro (5-10 ml. of blood) samples. For micro (0.25 ml. of blood) samples the State used an atomic absorption spectrophotometer with a Delve's Cup Attachment.[5] The State Laboratory has been cooperating with the Childhood Lead Poisoning Control Laboratory Monitoring Program of the Center for Disease Control, P.H.S., Department of Health, Education, and Welfare. This quality control procedure was begun prior to the New Haven screening program, and was effective throughout the years of this study. Based on the results of this monitoring mechanism, performance of the State laboratory has been evaluated as acceptable, or better.*
2. Yale-New Haven Hospital performed only macro tests among the screenees described herein, and conducted its own laboratory analyses using the atomic absorption method.[8] Occasional split sampling was used by Yale-New Haven Hospital to verify its results against the State Health Department standard method. The Hospital laboratory meets quality control standards established by the State laboratories Division. In addition, the Hospital laboratory conducted its own internal quality control procedure and participated in the Childhood Lead Poisoning Control Laboratory Monitoring Program of the Center for Disease Control.

The foregoing procedures were accepted as establishing the reliability of the laboratory methods, and test results were assumed to be accurate (within the accepted quality control limits) with respect to the samples as they reached the laboratories. However, the question of reliability of reported results required consideration of other possible sources of error. Contamination of a blood sample with external environmental lead could produce an over-estimate of the blood lead level. Since direct validation of blood lead results was not possible, indirect estimates of reliability had to be made.

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*(Personal Communication, J.S. Tucker, Ph. D., State Laboratory)

Reliability of the Macro Screening Method

The macro method was used as a standard. This was a reasonable decision because the likelihood of errors in sample collection are proportionately much smaller than are those for micro tests. Lead-free glassware and needles for collection of blood for lead determinations have been standardized for many years by the State. Macro determinations by Yale-New Haven Hospital were made by hospital staff, using rigorously prepared lead free materials. Staff of the City Health Department, the hospitals and other health providers followed standard techniques for cleansing the skin of children prior to venipuncture. Approximately 900 children from one through six years old received initial macro tests during the two and a half year screening program.

The Micro Screening Method: Description and Reliability Test Considerations

All sample collection by the New Haven Health Department was done by either of two individuals, a certified laboratory technician or a registered nurse who had been trained by the technician. The sampling technique was standardized as follows: the child's middle finger was thoroughly cleansed with a soap solution, rinsed and dried. The finger was then sprayed with collodion which was allowed to dry. A disposable lancet was used to puncture the finger from which approximately ten drops of blood were allowed to drip onto the filter paper which was then inserted into a plastic envelope. The envelope was sealed and refrigerated for a maximum of 24 hours before being mailed to the State Health Department Laboratory. Collections by other medical care providers were done by nurses, physicians, or trained technicians. Samples were collected in individual homes as well as clinics, hospitals and private care facilities.

The indirect method for assessing the reliability of the micro test results is based on the strong correlation between micro and macro test results obtained when samples are taken from the same subject.[9] It was not practicable to obtain simultaneous replicate tests on the same child for the purpose of comparison during the screening program. However, an indirect approach could evaluate the consistency of initial micro tests with initial macro tests, when test subjects were matched by age, sex, race and season. There was an inherent problem for such matching in the first six months of the program because children with symptomatic illnesses were more likely to be selected for macro than for micro sampling. However, the extent of this bias could not be quantified, and as the screening program progressed, these sicker children tended to be screened out, so that in the second and third years of the study, selection biases were probably minimal.

Table 1

BLOOD LEAD TESTS OF CHILDREN AGED 1-6 USED FOR RELIABILITY ESTIMATES, WITH CATEGORIES AND NUMBERS EXCLUDED

Total initial tests		8334
Selected for environmental study	377	
Chelation therapy	68	
Missing variables	1049	
Sub-total excluded		1494
Suitable for reliability evaluation		6840

The numbers of tests available for reliability estimates are summarized in Table 1. Of the 8,334 initial tests, 377 were from children selected specifically for environmental lead studies. They will be reported separately. Sixty-eight children were excluded because of chelation treatment which was not always recorded in relation to the date of the initial test within this screening program. An additional 1,049 tests lacked age or race information. The remaining 6,840 test results were available for reliability tests.

Age, race and season have been associated with variations in children's blood lead levels;[10] therefore, a valid comparison between micro and macro results would have to control for these variables. For each month and year where the number of children receiving macro blood-lead tests (and whose race and age were both known) totalled at least 15, the mean macro blood-lead level was compared to the mean blood-lead of a sample of micro tests performed in the same month. The micro comparison group for each month was selected by a computerized random number selection scheme to provide numbers of children in each age/race group proportionate to the distribution in the respective macro standard group. Ages were combined into two groups, less than 24 plus 48-72 months, the ages of lesser risk for elevated blood lead, and 24-47 months, the ages of greater risk. Because of the small numbers of children whose race was reported as "other", an "other" value for race was treated as if it were a missing value, and selection of micro tests was done to attain proportionality for age categories within the racial groups Black, White and Hispanic only. Sex was not a significant variable in this study, therefore male and female data were combined.

The random selection process reduced substantially the numbers of tests used for macro-micro comparison, but tended to assure that statistical tests would give results that would be valid for the entire dataset. The principal reason for not using data for a particular month was that there were too few *macro* tests to give representative numbers within the age and race subsets. Table 2 shows that 13 of the 32 months from July 1974-February 1977 had data suitable for test. In one

Table 2

COMPARISON OF MICRO AND MACRO BLOOD LEAD TESTS, CONTROLLING FOR AGE AND RACE

	Macro Test			*Micro Test*			
Date	*GM**	*GSD***	*n*	*GM*	*GSD*	*n*	*95% CI for GMmacro/GMmicro*
July 1974	34.58	1.44	92	23.70	1.57	92	(1.30, 1.64)
August 1974	36.15	1.32	85	28.66	1.35	170	(1.17, 1.36)
September 1974	38.70	1.41	36	28.14	1.31	36	(1.19, 1.59)
October 1974	31.11	1.44	58	28.48	1.36	58	(0.96, 1.24)
November 1974	31.68	1.41	39	29.16	1.36	39	(0.94, 1.26)
December 1974	29.59	1.44	19	27.95	1.37	171	(0.91, 1.23)
January 1975	26.03	1.44	18	27.99	1.28	108	(0.77, 1.12)
February 1975	28.46	1.43	22	28.16	1.28	110	(0.86, 1.25)
March 1975	27.75	1.30	15	29.55	1.28	90	(0.82, 1.08)
April 1975	25.13	1.47	25	28.83	1.26	150	(0.84, 1.03)
June 1975	27.60	1.59	19	31.59	1.24	76	(0.70, 1.10)
June 1976	25.80	1.53	16	30.97	1.39	54	(0.68, 1.02)
July 1976	31.03	1.55	20	30.47	1.39	44	(0.84, 1.24)

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*GM = geometric mean, ug lead/100 ml. blood.

**GSD = geometric standard deviation.

or more years, all months except May were represented, while June and July were each represented twice because screening was more extensive during summer periods.

A total of 464 macro tests were compared with micro tests, as indicated in Table 2.

Micro means by month were compared to macro means. A log transformation provided a normal distribution of values for statistical tests.[11] The results presented in Table 2 were re-converted to the original arithmetical scale.

Results

Table 2 results indicate only three months (July 1974, August 1974, and September 1974) where equality of the micro geometric mean with the macro geometric mean is not included in the 95% confidence interval. For these three months there were greater macro geometric means than micro geometric means for reasons already described, and this trend continued through December 1974.

Conclusion

The macro blood lead results have been assumed to be accurate. Comparison of micro blood lead results with macro blood lead results do not suggest contamination of micro samples as a source of significant error in micro test results in the New Haven screening program.

Our conclusion is that properly trained persons can perform micro tests in the community and provide results accurate enough for use in planning public health controls for community and household risks of lead exposures to young children. Regular quality control procedures should be used to maintain staff skills as well as laboratory methods at acceptable levels.

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Percutaneous Transluminal Angioplasty

Interventional Radiology

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Percutaneous transluminal angioplasty is a technique which employs a balloon-tipped catheter to relieve arterial stenoses and occlusions. Most often employed for dilatation of the iliac or femoral arteries, the procedure is designed to compress atheromatous material against the arterial wall with enlargement of the vessel lumen and improvement in distal blood flow. The case presented here illustrates the use of percutaneous angioplasty in the treatment of peripheral vascular disease.

Case History

A 56-year-old man was admitted for evaluation of left leg claudication. Symptoms had begun approximately one year prior to admission and had progressed to the point where severe left calf pain occurred after walking a distance of about 100 feet. The patient's history included several transient ischemic attacks, bilateral carotid endarterectomies, hypertension, and many years of cigarette smoking. Doppler studies prior to angiography revealed decreased flow to the left calf and ankle. This was confirmed on physical examination where weak popliteal, dorsalis pedis, and posterior tibial pulses were felt on the left.

Ileofemoral angiography was performed and showed patent iliac and femoral arteries bilaterally. However, a one centimeter long area of greater than 75% stenosis was found involving the left popliteal artery. (Figure 1). There was a pressure gradient of 70 mm of mercury across the stenotic region.

Percutaneous transluminal angioplasty was performed using a Gruntzig balloon catheter. The stenotic region of the popliteal artery was dilated. Repeat pressure measurements and angiograms at the end of the procedure demonstrated normal lumen site with relief of the pressure gradient. (Figure 2). The patient was maintained on anticoagulents, ambulated the following morning and was discharged asymptomatic, two days later.

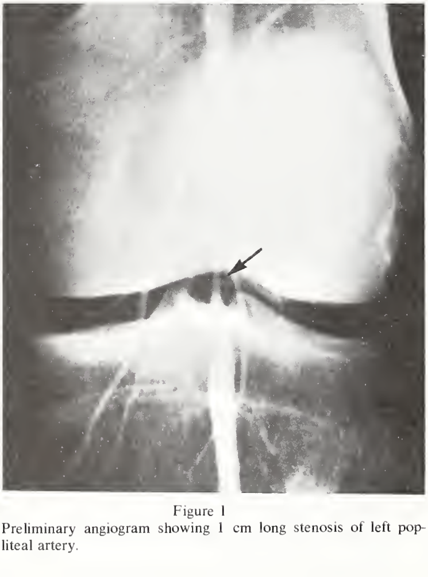

Figure 1
Preliminary angiogram showing 1 cm long stenosis of left popliteal artery.

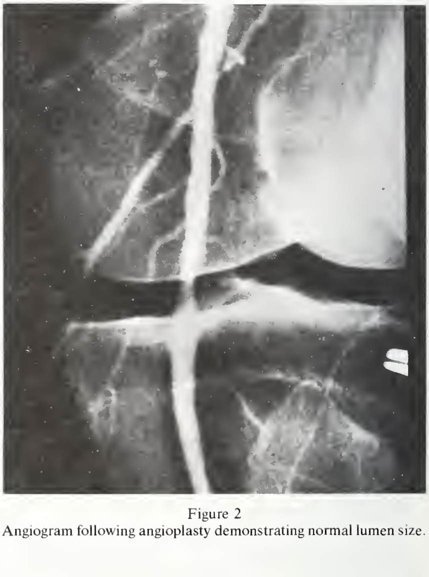

Figure 2
Angiogram following angioplasty demonstrating normal lumen size.

Discussion

The lesions most amenable to treatment by percutaneous transluminal angioplasty are short (1-5 cm), isolated, non-calcified stenoses of the iliac or femoral arteries. The advantages of percutaneous angioplasty

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over vascular surgery include a relatively low morbidity rate and decreased time of hospitalization.[1] In addition, patients who are poor candidates for general anesthesia can be treated by this technique. Complications of the procedure include arterial dissection and distal embolization. The incidence of these complications was 5% in one series of 300 patients[1] and 6.9% in a second series of 43 patients.[2]

Two year follow-up reports on 300 patients treated with percutaneous angioplasty reveal a patency rate of 87% for iliac artery lesions and 72% for femoropopliteal artery lesions.[1]

Although this technique appears to be quite effective as primary treatment of carefully selected cases of peripheral arterial disease, it is by no means a replacement for vascular surgery. Indeed, close cooperation between the angiographer and vascular surgeon is essential in formulating the optimum treatment plan for the patient.

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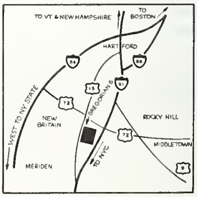

The Systemic Therapy of Urologic Cancer

JOHN C. MARSH, M.D.

The primary *curative* approach to cancers of the urinary tract and male genital tract (kidney, bladder, prostate and testicular cancer) is surgical, with radiation therapy also playing a prominent role. Nevertheless, at least one-third of all patients with urologic cancer (16% of all malignancies) die of their disease, and in these patients, systemic therapy can play a significant role, producing temporary regression, palliating symptoms and sometimes prolonging life. In recent years, systemic chemotherapy has played a dramatic role in curing many patients with non-seminoma testicular cancer. Unfortunately, testicular cancer comprises less than 4% of all urologic cancer and the progress in the other types has been less impressive. The use of *adjuvant* chemotherapy of urologic cancer is in its infancy and cannot yet be recommended for routine clinical use since controlled trials have not yet been done. In some instances systemic agents effective against advanced disease, which would be required for adjuvant therapy, are simply not available. However, urologic cancer is rather belatedly receiving an increased amount of well-deserved attention, and new drugs and combinations are being evaluated in controlled clinical trials.

Renal Carcinoma

In this country about 7,000 people develop kidney cancer annually. It is estimated that about 75% of them will die within ten years of diagnosis from distant metastases, although in some, the tumor may grow quite slowly. The most frequent sites of metastatic disease are lungs, bone, brain and liver. Cure depends on adequate surgical removal and the likelihood of cure is related to tumor size, involvement of perinephric tissues and the renal vein. Postoperative radiation therapy has been used to treat large bulky tumors without demonstrable proof of efficacy. Preoperative irradiation has not been shown to improve the therapeutic results. There is no role for adjuvant chemotherapy or hormonal therapy at the present time.

Because of the ability to induce renal adenocarcinoma in the golden hamster with prolonged estrogen administration, and the inhibition of this induction by the simultaneous administration of testosterone or progesterone, these latter agents have been utilized clinically. The best results have come from Bloom in England, utilizing medroxyprogesterone acetate (Provera).[1] He has reported an objective response in 16% of patients treated, with a more favorable response (21%) in men than in women (8%). If deaths within six weeks were excluded, the objective response rate in men was then 27%. Response durations were brief and incomplete. Unfortunately, even these modest results have not generally been confirmed elsewhere. At the West Haven Veterans Hospital, no responses were seen in 12 patients treated with Provera alone;[2] at the M. D. Anderson Hospital, 3 of 16 patients responded;[3] in a Swiss study, no responses were seen in 37 patients who were given progestational agents either alone or in combination.[4]

Androgens have likewise been disappointing. In the Swiss experience no responses were seen in 43 patients given androgens alone or in combination. At the West Haven Veterans Administration Hospital, one of 17 patients treated with androgen alone had a partial response, and three others had a "minimal response."[2] One of three patients given both androgen and Provera responded. The best responders were those with bone lesions. In a controlled clinical trial of the Eastern Cooperative Oncology Group, Medroxyprogesterone did not add to the antitumor efficacy of two nonhormonal agents, vinblastine or methyl-CCNU.[5]

It is tempting to use the above-mentioned hormonal agents because of their relative lack of toxicity, but it

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must be admitted that their efficacy is poor. There is also no satisfactory nonhormonal chemotherapy for renal carcinoma. Most of the well-known antitumor agents, active in other diseases have been evaluated in renal carcinoma, with very poor results. In the above-mentioned trial of the Eastern Cooperative Oncology Group the response rate to vinblastine was 10%, to methyl-CCNU 4%, to vinblastine plus Provera 8%, and to methyl-CCNU and Provera 11%. The sizes of the groups treated were 38 to 45 patients. Adding to the difficulty in evaluating the results of chemotherapy is the rather slow pace of this disease in some patients; 7-17% of the patients exhibited no progression during the course of treatment. CCNU (Lomustine) in a study from Roswell Park was reported to have a response rate of 20%, 4 of 20 patients responding.[6] Unfortunately, subsequent experience with this agent has not been confirmatory. A preliminary study reported responses in 4 of 14 patients with a program consisting of vincristine, Adriamycin, Provera, and BCG with mean durations of remission of three months.[7] One of 7 patients in the experience of the Southwestern Oncology Group responded to a combination of Adriamycin and cyclophosphamide.[8]

The anti-estrogen, tamoxifen, has been evaluated in two studies. No responses were seen in 12 patients treated in Philadelphia,[9] while 2 of 49 patients responded in a Southwest Oncology Group study.[10] Another 14 patients in the latter study were said to have improvement or stabilization of their disease, but this is unlikely to be significant.

In summary, the treatment of metastatic kidney cancer is dismal. Relatively innocuous hormonal agents occasionally produce slight benefit and the experience with nonhormonal agents is even more disappointing. Careful evaluation of new agents or agents which have not been adequately studied in this disease is fully justified, and entry into such Phase II studies should be encouraged. An example is the current Eastern Cooperative Oncology protocol which compares the new agents, PALA, (N-[phosphonacetyl]-L-aspartic acid), m-AMSA (4′-[9-acridinylamino](methanesulfon-m-anisidide) and indicine-N-Oxide. It should be remembered that several years ago the situation in the treatment of advanced bladder cancer was just as bleak as it is today for kidney cancer, but with the advent of new agents such as Adriamycin and *cis*-dichlorodiammineplatinum (DCDP), the picture is much improved.

Bladder Carcinoma[11 12 13]

The prognosis of bladder cancer is related to the depth of invasion of the tumor in the bladder wall, and also to the histologic grade of the lesion. The more deeply infiltrating tumors tend to be less well differentiated. Bladder cancers are generally understaged by clinical means. Preoperative irradiation appears to improve the survival of patients with invasive but operable lesions. Residual pathologic involvement of regional lymph nodes following such combined therapy indicates a poor prognosis, even in the absence of other obvious metastases. Metastatic disease is most common to pelvic lymph nodes, other pelvic organs, bones, lung and liver. The use of computerized axial tomography, or ultrasound examinations may aid in the detection of both recurrent disease and the response of known disease to therapy. Close collaboration between surgeon, radiotherapist and medical oncologist is critical for the adequate staging and management of advanced disease.

The role of chemotherapy may be considered in three contexts: intravesical therapy for superficial tumors, the treatment of overt recurrent or metastatic disease, and as adjuvant therapy to "curative" surgery and/or radiation therapy.[14] The most widely used agent for intravesical therapy, useful only for superficial tumors, is thio-tepa. Fifty to 75% of patients have a beneficial effect, depending on the size of the tumor. The prophylactic value of recurrent thio-tepa instillation following initial treatment is controversial. Bleomycin and Adriamycin have also been used.

Systemic agents with some documented activity in bladder cancer include doxorubicin (Adriamycin), 5-fluorouracil, bleomycin, methotrexate and *cis*-dichlorodiammineplatinum (DCDP), with the latter being perhaps the most active single agent.[15] The foregoing drugs are active against the transitional cell carcinoma seen in this country. It is of interest that hexamethylmelamine, which has activity against the predominantly squamous carcinoma, arising in Bilharzia-infected patients in Egypt, is not particularly active against transitional cell carcinoma in the United States. Complete responses to chemotherapy are rare, occurring in less than 10% of patients treated. The combined complete and partial response rate for DCDP is approximately 40%, and as yet, the addition of other agents has not been demonstrated to be superior to this agent alone, while they do add to toxicity, particularly myelo suppression. The reported response rate to Adriamycin ranges from 17-35% and to methotrexate, from 25-50%. It is not clear whether high dose methotrexate with Leucovorin rescue is better than low dose methotrexate. Cyclophosphamide, 5-FU, Mitomycin C, and an investigational agent, VP16, are less active. The median duration of chemotherapy-induced responses is about six months, and generally occurs after three-four weeks of therapy. A controlled clinical trial being conducted at Yale as part of a larger Eastern Cooperative Oncology Group study compares DCDP alone to the combination of Adriamycin, cyclophosphamide and DCDP. The major problems with DCDP include severe nausea and vomiting at the time of administration, hearing loss, and renal toxicity, which can be ameliorated, but usually not totally prevented, by induction of diuresis. Combination chemotherapy has yet to be shown to be more effective than single agents, but the combination above is a good one to test since the platinum compound has relatively little myelosuppressive effect, whereas both Adriamycin and Cytoxan do.

Adjuvant chemotherapy should be considered most strongly in patients who are at a high risk of recurrence. Patients subjected to total cystectomy and preoperative irration therapy, who still have positive lymph nodes, certainly are in that category, with a 5-year survival of perhaps 10-20%. Current adjuvant studies in such patients include the evaluation of DCDP alone, DCDP plus Cytoxan, Adriamycin and Methotrexate or a combination of 5-FU, Adriamycin and DCDP. An uncontrolled study seems to indicate the value of adjuvant chemotherapy with a combination of cyclophosphamide and Adriamycin, but the lack of controls casts doubt on this conclusion.[16] Although several studies are under way involving immunotherapy with BCG, injected preoperatively into the tumor, or with Levamisole as an immunostimulant, no conclusions are as yet possible. A protocol to evaluate the radiosensitizing effect of metronidazole (Flagyl) as an adjuvant to radiation therapy for advanced unresectable but nonmetastatic bladder carcinoma is in progress at our institution.

Prostate Carcinoma[17 18]

This is the most common cancer of men over the age of 50, and is by far the most frequent urologic cancer, with adenocarcinoma the usual histologic type. The incidence is age-related, and the cancer is more common in black than white men. The prognosis is a function of both clinical stage and tumor grade. Pelvic lymph nodes, paraaortic lymph nodes and bones are the major distant sites involved. The bone marrow is often involved by tumor. This fact plus the age of the patient and the frequent use of radiation therapy in the treatment of painful bone lesions makes cytotoxic chemotherapy poorly tolerated in many patients. Evaluation should include a bone scan, sometimes supplemented by bone x-rays, chest film, acid and alkaline phosphatase, bone marrow aspiration and intravenous pyelogram. Bone marrow acid phosphatase determination is still investigational and is often unreliable with routine methods. The value of lymphangiography is still controversial;[19] at Yale-New Haven Hospital it has not been very accurate.

Endocrine therapy for prostate cancer which is not curable by surgery or radiotherapeutic means has been in use for nearly 40 years, consisting either of orchiectomy or estrogen administration. Such therapy is appropriately reserved for Stage C (tumor localized to the peri-prostate area), Stage D_1, (tumor involving regional lymph nodes), or Stage D_2 (distant metastases). It is not curative, but responses are seen in 60-80% of patients with duration, degree and quality of response being unpredictable. Roughly, one-third to one-half of these patients will respond further to subsequent endocrine manipulation consisting of adrenalectomy, hypophysectomy, or "medical adrenalectomy" with an agent such as aminoglutethamide. The duration of favorable response to the secondary endocrine therapy is usually brief. These endocrine manipulations presumably alter the availability of androgen to the neoplastic tissue and thereby influence the ability of androgen to cause further proliferation. The eventual loss of response to endocrine manipulation suggests that, as in breast cancer, these neoplasms are heterogeneous, composed of both hormone-sensitive and hormone-resistant cells with the latter population eventually gaining the ascendancy.

Because of the success of the measurement of tumor estrogen receptor protein in predicting the response to endocrine therapy in breast cancer, it is natural to ask whether comparable androgen receptor protein assays are of clinical benefit in prostate cancer. Unfortunately, at the present time the answer is no. There are several reasons for this: the determination of androgen receptors has been significantly compromised by the presence of contaminating plasma proteins with high sex hormone binding affinity; the normal prostate gland, in contrast to the non-lactating normal breast, contains significant amounts of sex hormone receptor protein; much of the androgen receptor protein is already occupied by endogenous androgen. Although measurements of androgen-binding protein are being reported[20] for normal and hyperplastic human prostate, no data are yet available in prostate cancer which suggest that this measurement will be useful. Nevertheless, this is a possibility for the future. One might be expected to identify those patients who would benefit from endocrine therapy, and, perhaps more appropriately, by analogy with the situation which exists in breast cancer, would identify patients who would not be expected to benefit from such therapy, thus allowing the direct application of nonhormonal treatment, which at present is not ethically permissible.

The removal of the testicles produces a 90% decline in plasma testosterone levels. The administration of estrogen suppresses luteinizing hormone released by the pituitary gland, thereby indirectly suppressing plasma testosterone levels. One milligram of diethylstilbestrol (DES) is effective, however, in treating carcinoma of the prostate, but suppresses plasma testosterone levels incompletely and unpredictably. Three milligrams of DES does cause suppression of plasma testosterone levels into the ranges seen after castration, but is not known to be clinically superior to 1 mg. Estrogen also may inhibit testicular androgen formation, the metabolism of prostate cancer cells or increase the plasma concentration of testosterone binding globulin, thereby decreasing the *free* testosterone which is available to the neoplasm. In theory, the administration of estrogen to orchiectomized patients may have the undesirable effect of stimulating prolactin release by the pituitary which can then enhance the use of available androgen by prostatic cells.

Clinical Stage C prostate cancers comprise 40% of newly diagnosed lesions. By most definitions the serum acid phosphatase and the bone scan are normal. However, a large proportion of these patients (35-70%) may have involvement of regional lymph nodes, and lymphangiography is sometimes useful in demonstrating them. However, in our institution the results with lymphangiography in prostate cancer have been disappointing. Hormonal manipulation has not clearly increased survival in Stage C disease, but can certainly be palliative, and seems to be better than a placebo in terms of decreasing ureteral obstruction, ameliorating urinary symptoms, and causing a regression in palpable disease. External beam irradiation of the primary tumor and lymph nodes, however, is often used preferentially with irradiation of both the primary and lymph node bearing areas. For Stage D carcinoma, there appears to be little difference in ultimate outcome between orchiectomy or estrogen therapy. An increase in survival, comparing patients begun on estrogen or castrated at the time of diagnosis to those who are treated only when symptoms occur, cannot be demonstrated. The results of the VA cooperative study[21] suggest that estrogen is slightly better than orchiectomy in preventing cancer deaths, but the higher dose of estrogen (5 mg of diethylstilbestrol) was associated with an increase in cardiovascular deaths, while 1 milligram was not. The use of 3 mg has been advocated on the basis of more complete suppression of plasma testosterone, but the effect of this dose on cardiovascular deaths has not been evaluated. At the present time, it is reasonable to utilize 1 mg of diethylstilbestrol daily in the patient with Stage D disease, remembering to give a small dose of irradiation to the breasts to prevent painful and embarrassing gynecomastia.

Orchiectomy can be utilized for patients who are at serious risk from cardiovascular disease or who are not reliable about taking medication. It is common practice to use estrogen in orchiectomy failures, or to do an orchiectomy in estrogen failures, but data to substantiate increased survival are not available. There appears to be no justification for initiating both procedures at once.

The use of high doses of diethylstilbestrol phosphate (Stilphostrol) in estrogen failures sometimes results in responses at about the 40% level, lasting a few months.[22] Endocrine ablative procedures have also been used, including bilateral adrenalectomy and hypophysectomy. We prefer the latter operation in this hospital because of extensive experience, particularly in breast cancer, but it must be admitted that although the effects on bone pain can be dramatic for short periods of time with either of these operations, the durations of remission are usually brief.

Estramustine (Estracyt) is estradiol phosphate linked to nitrogen mustard by a carbamate bridge. It is clearly active in estrogen-resistant patients; objective responses ranging from 10-25% and additional subjective improvements or stable disease in another 40-60%.[23] Average response durations are about 8 months, and tend to be longer if patients have not received prior orchiectomy in addition to estrogen therapy. We did not observe better results when 5-fluorouracil was added to estramustine,[24] but other drugs are being evaluated in combination with it since it does not cause significant bone marrow depression, an advantage in patients who often do not have good bone marrow reserve, due to tumor infiltration or prior irradiation therapy. Occasional side effects include edema, gastrointestinal toxicity, gynecomastia, urticaria and hepatotoxicity.

The antiestrogen, Tamoxifen, has been reported to have a 23% response rate, with responses lasting a few months.[9]

Numerous nonhormonal chemotherapeutic agents have been evaluated in this disease, and those which had reported activity include Adriamycin, hydroxyurea, CCNU, cyclophosphamide and 5-fluorouracil. The response rates range between 5-25%, and are usually brief.[25] The new agent, cis-diamminedichloroplatinum (DCDP), in an unconfirmed report[26] has been reported to have a response rate of 43%, and an additional subjective response rate of 28% which, if confirmed, would make it the most effective single drug available. It should be kept in mind that toxicities with this agent include invariable nausea and vomiting, and potentially, hearing loss and renal toxicity. Combination chemotherapy has not yet been established to be superior to single agents, and in some studies seems distinctly inferior. One recent combination program employs melphalan, prednisone, vincristine, 5-fluorouracil and methotrexate, and had a 38% response rate.[27] A number of controlled chemotherapy studies are underway through the auspices of the National Prostatic Cancer Project, seeking to evaluate combinations of hormonal and nonhormonal agents, and adjuvant chemotherapy in patients who have had definitive surgical or radiation therapy for early disease.

Immunotherapy of prostate cancer cannot yet be said to play a significant role.

As it becomes possible to stage patients more accurately in the future, and to design carefully controlled clinical trials, it can be expected that earlier and more appropriate therapy, perhaps combining the best elements of hormonal and nonhormonal therapy, will be increasingly useful, and that significant advances in the survival and quality of life of prostate cancer patients will be achieved.

Testicular Cancer

While this tumor comprises only one percent of all male cancers, it is the most common solid tumor in men in the third and fourth decade. No other non-hematologic malignancy, with the possible exception of small cell carcinoma of the lung, is as responsive to chemotherapy; even large, bulky masses may disappear completely. Germ cell tumors comprise 93% of testicular tumors, and these in turn are divided into pure seminoma and non-seminoma, or mixed tumors. The former are usually curable by radiation therapy, while the latter are not, but are susceptible to a number of chemotherapeutic agents (Table 1) which, when used singly, produce partial remissions, but rarely produce complete remissions. On the other hand, when appropriate combinations are used, the complete remission rate approaches 60-70%, and about half of these patients are ultimately cured (>5 year disease free survival). Relapse from complete remission in this disease generally occurs within two years. A very significant development of recent years has been the utilization of serum markers for these tumors, the beta subunit of human chorionic gonadotrophin (BHCG) and alpha fetoprotein (AFP).[28 29] Seventy-five to 90% of patients with non-seminoma tumors have an increased concentration of one or both of these marker proteins. Lactic dehydrogenase (LDH) is also helpful in many patients. Elevation of these markers reliably reflects disease activity even when recurrence or residual disease is not otherwise apparent and should be considered an indication for treatment. It is fair to state that the current major clinical problem is not so much the induction of complete remission in this disease, but primarily one of maintenance of that remission, a situation analogous to that which holds in acute, non-lymphoblastic leukemia.

Proper management of the primary tumor in the testis consists of inguinal orchiectomy with en bloc resection of the complete spermatic cord. In this way the tumor is obtained for careful histologic diagnosis which should be done by meticulous sectioning since the tumor often contains mixed elements. Pure seminomas may be treated with radiation to the draining retroperitoneal lymph nodes. However, for non-seminomatous tumors, retroperitoneal lymphadenectomy is preferred by many physicians while lymphangiography, followed by radiation therapy, is another method of treatment which gives approximately comparable results. Patients with Stage II disease, with known positive lymph nodes, and residual tumor markers following therapy are certainly candidates for systemic therapy since they may be presumed to have residual disease. The place of adjuvant chemotherapy in marker-negative patients, however, following definitive early therapy is not defined, although controlled clinical studies are in progress. Although activity was seen for single agents previously, among the first combination chemotherapeutic regimens used in cancer was that of Li *et al.* at Memorial Hospital, employing a program of chlorambucil, methotrexate, and actinomycin-D.[30] Half of the patients treated responded, most of them with complete remissions, although relapses occurred subsequently in the majority. Mithramycin enjoyed a brief period of popularity as one of the most active drugs in the embryonal cell carcinoma variant, but is fairly toxic and has been replaced by combination chemotherapy. The development of bleomycin, a relatively non-myelosuppressive agent, was a milestone in the therapy of testicular cancer because it has an appreciable response rate and can be combined with other drugs with significant myelotoxicity. Samuels and his colleagues in the M. D. Anderson Hospital combined bleomycin with vinblastine and found a 76% response rate, 32% complete remissions.[31] More complete remissions were found subsequently with bleomycin being given by continuous infusion, compared to the earlier program using intermittent treatment. Patients achieving only a partial remission invariably relapsed, while more than half of the complete responders have had long survival and, presumably, are cured. The Memorial group has evolved a combination chemotherapy program utilizing another non-myelosuppressive drug, cis-dichlorodiammine platinum (DCCP), in conjunction with vinblastine, cyclophosphamide, bleomycin and actinomycin-D.[32]

Chlorambucil and Adriamycin have also been utilized in an induction phase with excellent results. Some of the most impressive results have been reported from the University of Indiana, utilizing DCCP, vinblastine and bleomycin.[33] The combination is capable of causing significant toxicity, including nausea, vomiting, nephrotoxicity, hair loss, hearing loss, weight loss, pulmonary fibrosis, and severe granulocytopenia, but the curative potential of the drug combination warrants this approach in all newly diagnosed patients.

This vigorous therapy should only be undertaken with access to facilities providing excellent supportive care, including granulocytes, platelets, respiratory support and dialysis, as well as intensive nursing and physician care. It is clear that the first drug treatment is the most important, for if complete remission is not achieved, cure is unlikely, with one exception. Sometimes pulmonary metastases of teratocarcinoma, which shrink but do not disappear completely, are found to be residual areas of teratoma when they are removed surgically.

Because of the toxicity of the agents used, many physicians prefer not to treat Stage II patients with chemotherapy until such time as a recurrence is found, either by development of measurable disease or elevation of tumor markers, such as AFP or BHCG. This spares already cured patients the risk of severe toxicity with chemotherapy and reserves it for those in whom disease develops.

Table I
USEFUL DRUGS IN THE SYSTEMIC THERAPY OF GENITOURINARY CANCER

Drug	*Dose*	*Indication**	*Acute side effects*	*Toxicity*	*Precautions*
Medroxy-progesterone acetate (Provera)	400-800 mg/week IM or PO	K	None	Occasional liver function abnormalities; occasional alopecia and hypersensitivity reactions	Use with care in presence of liver dysfunction.
Cis-platinum; *Cis*-diammine-dichloroplatinum (II); (DCDP): (Platinol)	50-120 mg/M^2 IV q 3-4 weeks	B, T, ? P	Nausea and vomiting	Nephrotoxicity, ototoxicity, mild myelosuppression, uncommon neurotoxicity, anaphylactic reactions	Induction of adequate hydration and diuresis (100-150 ml/hr), with mannitol and/or furosemide. Renal and auditory function must be monitored.
Doxorubicin (Adriamycin)	60-100 mg/M^2 q. 3 weeks	B, T	Nausea, vomiting, fever, local phlebitis, necrosis if extravasated, red urine (not blood)	Bone-marrow depression, alopecia, cardiac toxicity related to cumulative dose, stomatitis	Administer through running IV infusion; avoid giving to patients with significant heart disease, follow for EKG abnormalities and signs of heart failure.
Cyclophosphamide (Cytoxam)	500-1500 mg/M^2 as a single dose IV; or 60-120 mg/M^2 per day PO. dose decreased if severe leukopenia develops	B, T	Nausea and vomiting	Bone-marrow depression, alopecia, cystitis, amenorrhea, sterility	Maintain adequate fluid intake to avoid cystitis.
Methotrexate	40 mg/M^2 IV weekly	B	None	Bone-marrow depression, megaloblastic anemia, diarrhea, stomatitis, vomiting; alopecia less common, occasional hepatic fibrosis, vasculitis, pulmonary fibrosis	Adequate renal function must be present, and urine output must be maintained. Avoid aspirin on the same day.
5-Fluorouracil (5-FU)	500-600 mg/M^2 IV weekly or 500 mg/M^2 IV daily x 5 q. 4 weeks	B	Occasional nausea and vomiting	Bone-marrow depression, diarrhea, stomatitis alopecia. Occasional ataxia.	Decrease dose in patients with diminished liver, renal or bone-marrow function, or after adrenalectomy.
Diethylstilbesterol (DES)	1-3 mg PO daily	P	None	Gynecomastia, edema.	Use with caution in heart disease.
Estramustine (Estracyt)	600 mg/M^2 PO in 3 divided dose daily	P	Nausea, vomiting, urticaria	Gynecomastia (rare) or breast tenderness. Occasional diarrhea, congestive heart failure; rare myelosuppression	Use with caution in heart disease.
Tamoxifen (Nolvadex)	10 mg b.i.d. PO	P	Occasional nausea and vomiting	Occasional myelosuppression, weakness.	

Vinblastine (Velban)	6 mg/M^2 IV weekly	T	Severe, prolonged inflammation if extravasated; occasional nausea, vomiting, headache, and paresthesias	Bone-marrow depression, particularly neutropenia; alopecia, muscle weakness, occasional mild peripheral neuropathy, mental depression 2-3 days after treatment, rarely stomatitis	Administer through running IV infusion or inject with great care to prevent extravasation: decrease dose in liver disease.
Bleomycin (Blenoxane)	10-20 units/M^2 IV or IM weekly	T	Fever, chills nausea, vomiting; local pain or phlebitis less frequent	Skin: hyperpigmentation, thickening, nail changes, ulceration, rash, peeling alopecia Pulmonary: pneumonitis with dyspnea, rales, infiltrate can progress to fibrosis; more common in patients over 70, and with more than 400 units total dose, but unpredictable	Use with care in renal or pulmonary disease. Do not exceed total dose of 400 units.
Mithramycin (Mithracin)	25-50 µg/kg IV on alternate days for 3-8 doses or until toxicity developes	T	Anorexia, nausea, local irritation and cellulitits with extravasation	Bone-marrow depression, hepatic damage with decreased production of clotting factors stomatitis, azotemia.	Very toxic drug; its use on alternate days with strict adherence to monitoring of LDH, BUN, prothrombin time, and platelet count before each dose can increase therapeutic index by decreasing toxicity.

* K = kidney cancer
B = bladder cancer
P = prostate cancer
T = testicular cancer

Any patient with a testicular mass which is likely to be malignant should have blood drawn preoperatively and several days postoperatively for measurement of these serum tumor markers. The tests should be repeated following treatment of retroperitoneal nodes as well if the markers were initially positive. Because of the relative rarity of these tumors, patients should probably be referred to specialized centers for the aggressive staging and chemotherapy which is often required. It is unlikely that further therapeutic advances will develop at single institutions but that the important questions which remain will require inter-institutional cooperation. Current response rates with combination chemotherapy approach 90%, with complete remission rates of 60-70%. The question of maintenance chemotherapy with the same agents used for induction or the introduction of new cycling agents is a question that is being approached by cooperative group studies.

Pure seminomas occasionally (5-10% of cases) are associated with an elevated BHCG, but AFP elevation in pure seminoma has rarely, if ever, been reported. Elevation of either of these markers should suggest a non-seminomatous character of the tumor. Because of the marked radiosensitivity of pure seminomas, chemotherapy is seldom necessary. At the present time, for recurrent seminoma, it seems reasonable to use the chemotherapy which is useful in the non-seminomatous tumors, although sometimes alkylating agents alone suffice.[34] The anaplastic variant of seminoma tends to be more advanced anatomically than its anaplastic counterpart, but the prognoses are similar when corrected for stage.

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Antenatal Diagnosis

SPONSORED BY THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Assisted by the Office for Medical Applications of Research, NIH

Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A Consensus Development Conference on Antenatal Diagnosis was held at the National Institutes of Health on March 5-7, 1979. The purpose of the conference was to assess the state of the art of techniques used in prenatal diagnosis; the legal, ethical, and social and economic implications of their use; appropriate applications of these techniques at present; and needs for additional research on their use.

The NIH consensus development program brings together practicing physicians, biomedical research scientists, consumers, and others in an effort to reach general agreement on the safety and efficacy of a medical technology, whether it be a drug, device or procedure.

At the antenatal diagnosis meeting, three broad categories of obstetrical techniques were discussed:

- Predictors of hereditary disease and congenital defects. These include mid-trimester amniocentesis, fetoscopy, alpha-fetoprotein measurements, and ultrasound;
- Predictors of fetal maturity, including third-trimester amniocentesis and ultrasound; and
- Predictors of fetal distress, including monitoring during labor.

Before the meeting, task forces prepared preliminary reports on each of the three topics, summarizing the issues and giving recommendations. These draft reports were disseminated widely to obstetrical researchers, practicing obstetricians and gynecologists, lawyers, bioethicists, consumers, and voluntary associations concerned with pregnancy and childbirth. The reports prompted many people to submit written statements before the conference and provoked much debate during the meeting. As a result of this discussion, task force members reviewed and in some cases revised the recommendations made in draft reports. Final reports were published during the summer of 1979.

Predictors of Hereditary Disease or Congenital Defects

The 12-member Task Force on Predictors of Hereditary Disease or Congenital Defects, chaired by Dr. Michael M. Kaback (Professor of Pediatrics and Medical Genetics, U.C.L.A. School of Medicine) weighed the risks and benefits of amniocentesis and other procedures that enable physicians to recognize defective fetuses as early as the fourth month of pregnancy.

They recommended that health professionals responsible for the care of pregnant women should be aware of techniques now available for early diagnosis of fetal defects, and should be prepared to identify and advise couples who are likely candidates for prenatal diagnostic services.

Amniocentesis—a procedure in which amniotic fluid and fetal cells are drawn out of the uterus for study—is now a widely accepted clinical practice, the panel found. They recommended that any pregnant woman age 35 or older should be advised about the possibility

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NIH Consensus Development Conference Summary Vol. II.

EDITOR'S NOTE: For further information about the "NIH Consensus Development Conference Summaries," contact the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

of undergoing amniocentesis (for detection of chromosomal abnormalities in the fetus). Other situations in which a pregnant woman should be offered the option of amniocentesis are:

- if she has had a chromosomally abnormal child in the past;
- if three or more of her past pregnancies have ended in miscarriages, or if her husband's previous wife experienced several miscarriages;
- if she or her mate is known to have a chromosomal abnormality;
- if there is a history of Down syndrome or some other chromosomal abnormality in her family or her spouse's family;
- if she has male relatives with Duchenne muscular dystrophy or severe hemophilia, or if she is suspected of carrying some other harmful gene on one of her X chromosomes;
- if her fetus is at a higher-than-usual risk for some hereditary error of metabolism detectable in utero; or
- if her fetus is at increased risk for a neural tube defect.

Although a physician may inform a woman that she is at higher-than-usual risk of bearing a defective child and may acquaint her with the existence and uses of amniocentesis, the final decision to undergo the procedure must be her own, the panel stated. Health care professionals should provide patients with the information they need to make such decisions.

Echosonography (ultrasound) is a valuable technique for viewing the fetus and placenta prior to amniocentesis, according to the panel, which strongly recommended its use in this context. However, more clinical research will be required before ultrasound can be relied upon as a tool for diagnosis of physical defects in its own right.

Fetoscopy and fetal blood sampling remain experimental and are not ready for general use at this time, according to the panel. These techniques carry a higher risk to the fetus than do amniocentesis or echosonography, and should not be used in situations where safer methods would suffice.

Measurement of alpha-fetoprotein (AFP) in amniotic fluid is now an accepted practice for detecting neural tube defects in pregnancies at special risk for these disorders, the panel found. It may soon be possible to screen large numbers of pregnancies for neural tube defects by measuring AFP in the blood serum of obstetrical patients; however, this screening procedure cannot be recommended for wide use until pilot studies prove its efficacy.

Predictors of Fetal Maturation

Ultrasonography and third-trimester amniocentesis are valuable, effective tools for determining fetal maturity in high-risk pregnancies and in other pregnancies where the baby may have to be delivered before term. In fact, appropriate use of these techniques can virtually eliminate the problems of prematurity and respiratory distress syndrome (RDS) following scheduled cesarean section, problems which have complicated 15 percent of such deliveries. However, these procedures should be used only when indicated, and should be studied further for possible long-range effects on both mother and fetus.

These were among the recommendations made by the Task Force on Predictors of Fetal Maturation, which discussed obstetrical techniques used to determine the age of a fetus and whether its lungs are mature enough to permit survival outside the uterus. Two such techniques are available: ultrasonography, and amniocentesis in the last three months of pregnancy. The amniotic fluid can be analyzed for certain components that indicate lung maturity by using either the L/S ratio test or the "shake test."

Panel members agreed that the potential benefits of both techniques in preventing premature deliveries far outweigh the costs and possible risks. However, because the long-range effects are unknown, the panel recommended against routine use of ultrasound for all pregnant women and cautioned that both ultrasound and third-trimester amniocentesis should be used only when indicated: in high-risk pregnancies, in cases where the woman has had previous cesarean sections, and in other cases where the physician thinks information on fetal maturity may be needed. Their specific recommendations were:

- If the patient's obstetrical history suggests that a cesarean section may be necessary, a sonogram should be taken before the 26th week to measure the fetal biparietal diameter (head width), an indicator of fetal maturity. If there is still some question about the age of the fetus, a second sonogram should be taken early in the third trimester; together, the two measurements provide the baby's growth rate, and can be used to accurately estimate its age.
- If the high-risk pregnant woman is not seen until later in pregnancy, ultrasound is not as accurate for judging fetal age and amniocentesis should be used to obtain reliable information on fetal lung maturity. (The panel recommended sonography to determine the position of fetus and placenta before amniocentesis.) Of the two tests that can be done on amniotic fluid—the L/S ratio test and the "shake test"—the panel said the L/S ratio is a more reliable indicator of fetal maturity. In both the L/S ratio and shake tests, there is an intermediate range of values which are hard to interpret and therefore unreliable predictors of whether a baby will develop RDS. However, with an L/S ratio of 2 or greater, there is a better than 99

percent chance that the baby will not have RDS.

Panel members pointed out that both methods require considerable expertise for accurate results—the shake test in particular is prone to inaccuracy when performed without caution. To minimize problems, the task force recommended post-graduate training in amniocentesis and ultrasonography for physicians with no experience in doing the procedures, and special care in performing the laboratory tests.

Suggesting directions for future research, task force members said there is a need for more accurate indicators of lung immaturity because of uncertain middle-range values in the L/S ratio test. They cited the "lung profile" and other measures as promising developments. Also, standards are needed for the manufacture of ultrasound machines and for both technical and professional proficiency in doing ultrasonography and amniocentesis.

The task force was chaired by Dr. Joseph Dancis, Chairman of the Department of Pediatrics, New York University School of Medicine.

Predictors of Fetal Distress

Agreement was reached by the Task Force on Predictors of Fetal Distress that, at present, the use of electronic fetal monitoring (EFM) should be strongly considered in high risk patients. Among the specific circumstances which the task force felt could benefit from the use of electronic fetal monitoring are expected low birth weight, premature, postmature or intrauterine growth retarded babies; women with medical complications of pregnancy; the presence of meconium in the amniotic fluid; and situations where abnormal fetal heart rate is detected with a stethoscope (auscultation).

In the absence of identifiable risk factors, the task force found periodic auscultation* of the fetal heart rate to be an acceptable way to assess fetal condition for women at low risk for complications during labor and delivery. The panel pointed out that present data are inadequate to permit final conclusions, but found no evidence at present that electronic fetal monitoring reduces mortality or morbidity in low risk patients. Nonetheless, it recognized that under certain circumstances, mothers or physicians may choose to use EFM even in low risk situations.

In any case—whether or not EFM is employed—the task force emphasized that EFM should not be a substitute for clinical judgment. Any form of monitoring, the panel said, is only one measure of fetal status.

Since unexpected complications may arise during labor, the panel said that all hospitals and birthing centers providing maternity care should have the necessary trained staff and equipment to assess carefully the status of each fetus during labor and to take appropriate action.

The panel also strongly urged that fetal scalp blood pH determination be used as an adjunct to electronic fetal heart rate monitoring. Scalp blood testing provides additional information that may reduce monitoring-associated cesarean rates.

The task force cautioned that when electronic fetal monitoring is used, personnel should be well versed in the potential hazards. To minimize risk, the task force recommended that:

1. Placement of the fetal scalp electrode and intrauterine pressure catheter should be performed very carefully and with the thorough understanding of the proper techniques to minimize risk of infection and injury to both mother and child.
2. Prolonged supine position of the mother should be avoided.
3. Maternal mobility should not be unnecessarily limited.
4. Artificial rupture of the amniotic sac solely for internal electronic fetal monitoring should not be routine.

The task force recognized that electronic fetal monitoring may be considered intrusive by women who want a natural, family centered birth. For this reason, the group said that the proper use of EFM should include a discussion with the patient of her wishes, concerns, and questions about all forms of fetal monitoring. The panel recommended that women have the opportunity to discuss the subject during the course of prenatal care and again upon admission to the labor suite.

The task force also identified some specific areas where additional research is needed. These include:

1. Research into the effects of hypoxia (decreased oxygen supply) on the fetus and newborn.
2. Research to identify risk factors for fetal distress during birth, especially fetal distress which is amenable to EFM.
3. Additional clinical trials of EFM in various categories of high risk patients to gather data on criteria for use, efficacy, and risk.
4. Development of non-invasive methods of fetal monitoring.

The Task Force on Predictors of Fetal Distress was chaired by Dr. Frederick P. Zuspan, Professor and Chairman of the Department of Obstetrics and Gynecology at the Ohio State University College of Medicine.

The Consensus Development Conference on Antenatal Diagnosis was sponsored by the National Institute of Child Health and Human Development, assisted by the Office for Medical Applications of Research, NIH, and the Fogarty International Center, NIH.

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* The panel defined periodic auscultation to include auscultation of the fetal heart every 15 minutes during the first stage of labor and every five minutes during the second stage. In either case, the fetal heart should be auscultated within 30 seconds of the end of a contraction.

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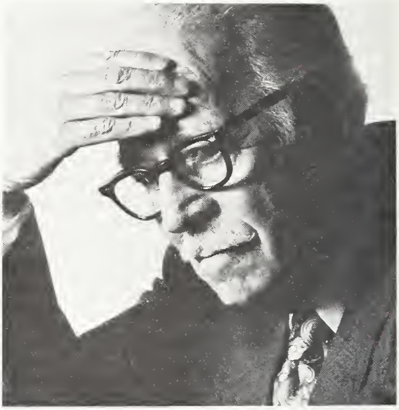

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Francis H. Williams and the Shadows of Disease

JOHN A. KAUFMAN

ABSTRACT—Shortly after Wilhelm Roentgen announced his discovery of x-rays to the world, physicians began to experiment with the new rays in medicine. Predominantly, they were surgeons interested in observing bony growths and abnormalities. They could see no further applications for x-rays. Francis H. Williams, however, was immediately impressed with the x-ray's potential use as a diagnostic tool. Working in Boston at the turn of the century, he created a science of radiology. This paper examines his work, and attempts to draw a conclusion as to why Williams' vision of x-rays was different than that of his peers.

Francis H. Williams was one of the earliest American physicians to utilize x-rays in medicine. Unlike most practitioners, however, Williams developed the discovery as a legitimate diagnostic tool rather than simply as a visual probe prior to surgery. The work he did in 1896 illustrates his unique approach. Of considerably more interest are Williams' reasons for turning to x-rays just weeks after Roentgen personally announced his discovery. Although he left no personal documents, Williams' previous published work, and that which he did with x-rays in 1896, gives some insight into his motivations.

The medical value of x-rays was apparent immediately, for one of the most convenient objects to hold in front of an excited cathode ray tube was one's hand. Seeing the bones through living flesh was as potent a demonstration of the properties of the rays the public could hope for, and figured in almost every early report. While it had been physicists, photographers and tinkerers who had started the initial experiments, doctors soon appeared at their laboratories with questions and patients. As one Boston physician wrote in 1986:

> During the last month (June) the electricians have published little about the Rontgen-ray phenomena. Edison and Telsa, having succeeded in taking photographs of the skeleton and shown wonder to the public, have handed over further elaboration to the medical men . . .[1]

The attitude with which most doctors approached x-rays was not significantly different from that of the non-medical workers. The emphasis was placed on looking at gross abnormalities already known to exist, such as old fractures, fused joints, and lodged bullets. Little attempt was made to arrive at a diagnosis on the basis of an x-ray examination alone, for most diseases and trauma of the bone, as understood in the late 1890's, could be identified by other means.[2]

The limited application of the x-ray was due, in part, to the difficulties of operating the machinery and obtaining usable photographic or fluoroscopic images. The technical limitations of the x-ray equipment were felt sharply by all associated with the medical applications of the discovery:

> Many details in the manipulation of the various parts of the apparatus have to be attended continually, and the best results are obtained only when all the various parts are carefully and properly balanced. When the cathode is large the tube seems to be more powerful for the time, but it wears out soon—i.e., its exhaustion gets so high that the largest coil will produce no discharge through it. Under these circumstances it has to be re-exhausted to the proper degree. It is clear, then, that the conditions necessary for the very best results cannot be realized very long at a time.[3]

However, it was perhaps the interests of the physicians that most influenced the way in which they used

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JOHN A. KAUFMAN, Boston University School of Medicine, class of 1982; B.A., Yale University, 1978.

this new tool. The x-ray's appeal was strongest to those who could benefit most from seeing the shadowy outlines of bones—the surgeons. What better probe before surgery than one's own eyes? In a relatively quick and painless manner, surgeons could now locate and visualize foreign objects or fractures without making a single incision. The surgical uses of x-rays were simply their most obvious application, and surgeons quickly became the most frequent users of Roentgen's discovery. Little work was done to determine the x-ray's effectiveness for examining soft tissues.

Dr. Francis H. Williams' accomplishment is most impressive in this light. He was one man possessed of an intent to develop x-rays beyond the surgical applications which were so common. First, let us examine just what Williams did that was different from other physicians' work with x-rays.

Williams started out in a manner characteristic of all early workers in x-rays, with the assistance of interested scientists and non-medical technicians. In his own words, written in late April 1896:

> During the past two or three months I have been much interested in studying the x-rays, and with the assistance of Mr. C. L. Norton and Mr. R. R. Lawrence, of the Massachusetts Institute of Technology, who have been investigating the x-ray problem in the Rogers Laboratory of Physics, have tested the application of x-rays to medicine in various ways.[4]

He seems to have used the standard Crookes' tubes that were available at the time. Williams was fortunate, however, to have been associated with Dr. William Rollins, a Boston dentist, who imposed a significant modification on the apparatus supporting his tubes.[5] On Rollins' instructions, the vacuum tube was placed in a box lined with white lead. One small opening was cut, through which the x-rays emanated. This single contribution prevented Williams and his patients from suffering the consequences of overexposure to x-rays, which killed many of his peers.

Rather than the more popular photographic plates, Williams used a calcium of tungstate fluoroscope, designed by T. B. Kinraide, that was free of any residual image.[6] As an additional precaution, Rollins placed a lead-glass plate over the screen, effectively cutting off all radiation which might have passed through. Again, Williams owed his life to Rollins.

The first report to come from the M.I.T. laboratory appeared in the form of a letter in the 30 April, 1896 edition of the *Boston Medical and Surgical Journal.* Williams reported that the group had started with the typical x-rays of hands and other convenient extremities, but as of late had attempted "to make the rays pass through the body; and recently this was attained, when Mr. Norton saw in a dark room by means of the fluoroscope the ribs and backbone of an adult." Later that same night, Williams examined Norton,

> and saw, besides his ribs and backbone, that the lighter portion of the area of the lung was limited below by a darker outline at about the height of the fourth rib, and that this outline moved up and down with expiration and inspiration. Evidently this was the upper border of the liver.[7]

What occurred in Williams' mind that night can still be felt in the letter 80 years later, for his dry scientific manner hardly conceals the intellectual excitement he experienced.

By the end of 1896 Williams had moved to the basement of the library of the Boston City Hospital. He was now able to differentiate the symptoms of tuberculosis, pneumonia, pleurisy, thoracic aneurism, emphysema and edema of the lungs with the fluoroscope.[4] While most other physicians were only philosophizing about the possible uses of x-rays in medicine, Williams was studying the changes in the fluoroscopic appearance of the thorax in disease, and attempting diagnoses based on this knowledge. His major contribution to medicine lies here, in a systematic study of the x-ray phenomena of the body.

Williams' research was founded on two assumptions about the nature of x-ray absorption. First, he reasoned that x-rays would penetrate variably according to the sheer bulk and/or chemical composition of the organs. And second, as the density and compounds present in an organ change with its pathological condition, its fluoroscopic appearance should also change.[4]

To test his assumptions, Williams performed a wide range of experiments utilizing all available materials. X-raying a tuberculous lung next to a healthy specimen (obtained from autopsy), he found by direct comparison of the two images that the diseased lung appeared darker than the healthy organ. By placing a number of chemical compounds found in the body on the photographic plate, he discovered the relative x-ray densities from the darkness of their images. Extrapolating this information with the known concentrations of the chemicals in the various tissues, Williams was able to qualitatively predict the visibility or invisibility of organs when viewed with a fluoroscope. He tested the absorptive properties of water, several body fluids, and air, relating the results to the volumes used and the chemical composition.[4] Above all, however, he examined patients whose illnesses had been diagnosed by other means, and made a careful note of what he found:

> One of the most interesting cases was that of a patient suffering from tuberculosis of the right lung, who was under the care of one of my colleagues at Boston City Hospital . . .
>
> After looking at him from behind for a mo-

> ment, the difference in the amount of rays which passed through the two sides of the chest was very striking, as seen through the fluoroscope. The diseased lung, as I had predicted, being darker throughout than the normal lung[7]

As often as possible, he compared the pathology of the organs at death with what he had seen in the fluoroscope.

Williams' attention was not limited to radiological features which would appear equally well through the fluoroscope or on a photographic plate, as do all those mentioned above. In actuality, his stated preference was for the fluoroscope when examining a patient. Symptoms of thoracic and cardiac disease frequently manifest themselves in some alteration of the constant motions of inhalation and exhalation, systole and diastole. Williams noticed this early on in his investigations, and established the now standard procedure of estimating organ displacements based on accepted norms.[6]

One could continue listing the work which was unique to Williams' approach for the entire length of the paper, for in that first year he anticipated almost all the fundamentals of modern x-ray diagnosis. In developing his technique of chest diagnosis, he formalized the essential tenet of the entire field of radiology:

> To use the Rontgen rays successfully in practice, it is first essential that the physician become familiar with the appearances in the fluoroscope which present themselves in health.[4]

Williams acted where others had only speculated, and acted first.

The question now arises, why was Williams so attracted to x-rays? As was hinted earlier, Williams was not a surgeon, but rather a medical physician. What made him different than other physicians who ignored, or were blind to the potential of x-ray diagnosis? Unfortunately, there is no direct means of gaining such an appreciation of Williams' attitudes toward, and motivations in, medicine. None of Williams' personal papers have been located; among those scholars who have looked into his life, their existence is doubted. What remains are his published works, written exclusively on medical subjects for a professional audience. Information culled from these provides the basis for the following examination of Williams' motivations for turning to x-rays in early 1896.

Williams spent his entire life in Boston, from 1852 to 1936. He was educated at the two most prestigious universities in that area: the Massachusetts Institute of Technology and the Harvard University Medical School. Between 1877 and 1879 he studied in Europe, and upon his return to Boston he immediately set up practice.[8] In 1884, he was appointed Instructor of Materia Medica at Harvard Medical School. Over the course of the next few years he rose to the position of Assistant Professor of Materia Medica and Therapeutics, as well as a visiting Physicianship at the Boston City Hospital. He was already a member of the elite American Association of Physicians in 1896, by merit of his achievements before his work with x-rays.[8] In the mid 1890s, Williams was an established physician of some repute, interested primarily in the treatment of disease.

Because Williams attended M.I.T. as an undergraduate, it is sometimes assumed that he was naturally inclined toward physics, and therefore more receptive to Roentgen's discovery.[2] However, what we do know of his interests as an undergraduate offers no support for this image of Williams as half physicist, half physician. Williams' senior thesis at M.I.T. was a fairly qualitative, unremarkable summary of some independent researches in organic chemistry entitled *On the Synthesis of Hydrocarbons by the Treatment of Cast Iron With Acids.**

If one were to draw any inferences from this sample of his academic interests as an undergraduate, they would be more indicative of the work he was to do before he turned to x-rays, rather than of his later work. What Williams had gained from attending a polytechnical school was a ready access to the available equipment and laboratory facilities. The hypothesis that a natural inclination towards physics, manifested by enrollment at M.I.T., made the application of x-rays to medicine a logical step for Williams must be rejected.

The key lies in Williams' medical work prior to 1896. To gain some understanding of interests, one must look only at his publications from 1894 and 1895. Williams wrote twenty-three articles during these two years, ten of which were concerned with diphtheria, and seven with diabetes mellitus.[10] According to the *1897 Annual Report of the Massachusetts State Board of Health,* diphtheria was the seventh greatest killer in the total population in 1895, and sixth in 1894.[9] Among children it was probably the greatest single slayer of the time. For diabetics, there was no insulin. This disease was a dreaded and fatal disorder.[11]

Clearly, Williams was concerned with the major medical problems of his day. His primary interests were in conditions that were both widespread and fatally beyond the capabilities of current medicine

If one looks beyond the titles, the content of Williams' articles reveals a far more significant trait; a receptive attitude towards, and a readiness to assimilate, new developments in medicine. He constantly discussed the treatments of disease, and in cases of diphtheria and diabetes, the newer chemical methods which were then being developed. Williams was the first physician in Boston to administer the diphtheria antitoxins developed in Europe at the beginning of the decade.[8] For the treatment of diabetics, he touched on such varied subjects as a diabetic flour, the danger of anesthetizing diabetics, and the uses of levulose and inulin in therapy. Although Williams' interest in organic chemistry and Materia Medica is reflected in these articles, a generally responsive approach towards new means of contending with disease is clearly the underlying theme.

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* Unpublished material in the Countway Library of Medicine, Holmes Room.

We can now understand why Williams, whose background was medical rather than surgical, was so attracted to x-rays. In 1895, chest disease claimed 14,307 lives in Massachusetts, almost 27% of the total mortality.[9] In 1896, Francis Williams saw in Roentgen's astounding new discovery, the potential for a powerful tool with which to combat these diseases.

Writing in late April 1896, Williams almost waxed poetic when describing the value of x-rays:

> The application of x-rays to surgery has hitherto formed the prominent side of their usefulness; I have pursued my investigations believing that it would be possible to demonstrate their usefulness in medicine, as distinguished from surgery, and am now confident that the advances these x-rays render possible in medical diagnosis are great, and that they will prove a more valuable instrument in the hands of the physician than of the surgeon. I have found them especially useful in diseases of the heart and lungs. We may now look where we have previously only been able to listen, and sometimes to hear but imperfectly. The advance consists not alone in what we can now see that we could not see before, but also in that we can by hand and ear and eye together strengthen and confirm these separate observations beyond their respective limitations; singly, they are beams, together an arch which justifies a heavier weight of inference.[12]

Due to a combination of his concern for the major diseases of his time, and a receptive mind for new medical developments, Francis H. Williams comprehended the critical role that x-rays could play in the diagnosis of the major diseases of his day. Creating guidelines and procedures for the x-ray diagnosis of thoracic diseases, he touched upon most of the fundamentals of modern radiology. Williams can perhaps be considered the first, and the greatest, of the American radiologists.

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Robbins vs. Medical Staff Physicians and Hospital

Dr. Frank T. Robbins and Robbins Clinic, Inc., Plaintiffs
vs.
Dr. Antonio Ong, Dr. Cecilia Ong, Dr. Victor Bautista, Dr. Grace Bautista, Dr. Ruben Silan, Dr. Chen Shih, Dr. Wu Jeng, Dr. Humberto Munoz, the Hospital Authority of Liberty County and William J. Verross, Defendants

United States District Court (Georgia)

June 8, 1978

Order on Plaintiffs' Motion for Preliminary Injunction

In this suit, plaintiffs claim that the defendants have conspired for three years to deprive the plaintiff, Dr. Robbins, and, as a consequence, Robbins Clinic, Inc., from the medical practice in Liberty County, Georgia. They also allege that the defendant physicians and the Authority have entered into a combination in restraint of trade by not renewing Robbins' hospital privileges. The Chairman of the Hospital Authority is alleged to be a part of the conspiracy.

Dr. Robbins further contends that the Authority denied him due process in the consideration and denial of his application for renewal of his privileges.

This Court entered a temporary restraining order on November 10, 1977, under which the Hospital Authority was restrained from revoking or refusing to renew Dr. Robbins' hospital privileges. An evidentiary hearing on the application for a preliminary injunction was held on December 9 and 10, 1977. The question of whether to grant preliminary injunctive relief is the only issue immediately before this Court.

I

Dr. Robbins contends that the defendant physicians have conspired against him by refusing to follow established referral policies. He also contends that the doctors and the Hospital Authority have and are conspiring to deny the renewal of privileges.

The evidence indicates that prior to 1974, Dr. Robbins and one or two other physicians were the only medical practitioners in Liberty County. Some time in 1974, what the plaintiff characterizes as "foreign" doctors started practice in Liberty County. Eight of these physicians are defendants in this action.

The record reflects a history of incidents involving Dr. Robbins and the Hospital administration. Three were considered by the Authority at a meeting on September 9, 1976. They involved interruption of a training class, failure to be "readily available" while on emergency room call, and refusal to care for another doctor's patient. The members of the Authority thereafter met and reviewed the recommendation of the Medical Staff that Dr. Robbins' privileges be revoked. Dr. Robbins was represented by counsel at this meeting.

After reviewing the evidence, the Authority sent Dr. Robbins a letter dated November 4, 1976. (Defendants' Ex. 3). It stated:

> "The Authority is seriously disturbed by the obvious conflicts between Dr. Robbins and other members of the Medical and Dental Staff. Cooperative attitudes are essential to the proper and efficient operation of any entity, and this is especially true in the case of a hospital. The Authority intends to pay close attention to any influence which might be considered detrimental to hospital operations. Uncooperative attitudes demonstrated by any member of the Medical and Dental Staff or any employee of the hospital will not be tolerated.
>
> "While the Authority expresses its extreme disappointment in the conduct and attitude of Dr. Robbins disclosed in the transcript of record, it is the decision of the Authority to deny the recommended revocation of Dr. Robbins' privileges at the hospital, but the Authority expects Dr. Robbins, all other members of the Medical and Dental Staff and all employees of the hospital henceforth to work together in harmony and in a cooperative spirit, in order that the hospital may continue to offer to the public that quality of care which the public has a right to demand."

At a meeting on July 19, 1977, the Authority again discussed Dr. Robbins' status at the Hospital. He was present. The specific item under discussion was Dr. Robbins' refusal to allow a new Registered Nurse, Nina Garcia, to work in the operating room with him.

EDITOR'S NOTE: All legal citations are deleted.

Dr. Robbins explained his view of the incident. After he left the meeting, the Authority considered a recommendation not to renew Dr. Robbins' privileges.

According to the minutes of that meeting (Plaintiffs' Ex. 8), Mr. Verross stepped down as Chairman and recommended that Dr. Robbins' privileges not be renewed. It appears that he had prepared a list of thirteen incidents involving plaintiff. None of them involved medical competence. He had also prepared a written recommendation to the Authority which stated:

> "RECOMMENDED ACTION AFTER CONSIDERATION BY THE HOSPITAL AUTHORITY OF THE DATA HERE PRESENTED.
>
> Dr. Frank T. Robbins' privileges in general practice, general surgery and emergency room are valid through November 30, 1977.
>
> Therefore, I recommend that the Authority put Dr. Frank T. Robbins on notice that *if* he applies for renewal of privileges at Liberty Memorial Hospital, effective December 1, 1977, the Authority will not grant him privileges in Liberty Memorial Hospital, asserting that we must take this action for the common good of the public and the hospital. In the Authority's considered judgment, Dr. Robbins' personality and demonstrated behavior during the last two years indicates that he cannot, or at least will not, change his behavior for the better.
>
> This is not to say I recommend that the Authority find him, or even imply that he is, an incompetent physician. Quite the contrary. He is an extremely able physician who unfortunately cannot confine his actions to being a good doctor, or to get along with most of his fellow men. I do not recommend the suspension of, or even call for the consideration of, Dr. Robbins' license to practice medicine. All thirteen recorded incidents are of a nonmedical nature. Dr. Robbins has the opportunity to use the next four months to rearrange his practice at places other than Liberty Memorial. It is in the best interests of many people of Liberty County who are Robbins' patients that he continue to operate his clinic in Hinesville. I do not call for this unusual decision by the Liberty County Hospital Authority in an arbitrary or capricious manner. In my opinion, Dr. Robbins has amply illustrated that he cannot get along with the Administrator and other hospital management, he cannot get along with the Medical Staff, nor can he act in a civilized manner towards a majority of the nurses and other professional technicians of Liberty Memorial Hospital. For many years when there were only Drs. Fraser and Robbins to provide medical service to the citizens of Liberty County, I urged the staff, and management, and the Authority, to turn the other cheek, so to speak, in behalf of all the sick people of Liberty County. Now that an adequate number of competent physicians are practicing in Liberty County, and are on our Medical Staff, there is no justification for this Authority to ask the management, or the Medical Staff, or the hospital staff to put up with Dr. Robbins' behavior any longer. We owe this to the persons who have suffered, and to those professionals who will come with us in the future."

After a discussion, the Authority unanimously adopted the recommendation. Chairman Verross sent Dr. Robbins a letter dated July 19, 1977 (Plaintiffs' Ex. 2) which stated that the Authority had "reviewed a twenty-six month record of your offensive and unsatisfactory behavior." It concluded that it was "the considered decision of the Hospital Authority that if you apply for renewal of . . . privileges at Liberty Memorial Hospital, effective December 1, 1977, you will not be granted said privileges."

On October 5, 1977, the Credentials Committee, consisting of two of the defendant doctors, recommended that Dr. Robbins' privileges not be renewed. The reason given was that his "personality and behavior have become incompatible" with the Authority, a majority of the medical and hospital staff, and the hospital management "to the prejudice of good order and efficient functioning of the hospital." (Plaintiffs' Ex. 3).

The medical staff voted to accept this recommendation on October 6th. Authority Tr. 27-33. This suit was filed a few days later.

On October 25th Dr. Robbins was notified of the decision of the medical staff. The letter informed him that a hearing on the decision would be held before the Authority on November 16th at which time he could have counsel present. The letter listed seven incidents which would be reviewed at the hearing. Five of them were included in Mr. Verross' list. Two of the seven incidents occurred after the meeting of the Authority on July 19, 1977.

The hearing before the Authority lasted three days. The transcript thereof is nearly eight hundred pages long.

On December 8th, the Authority issued an opinion. (See Court's Ex. 2). It found that Dr. Robbins had acted improperly in all of the seven incidents set forth in the letter of October 25th. It was specifically found that Dr. Robbins threw a scrub brush outside the operating room and shouted abusively. Second, Dr. Robbins refused to permit Nina Garcia, a qualified hospital employee, to be present while he was in the operating room. Third, he was unwarranted in interrupting a nurses' training session. Fourth, he verbally abused two hospital employees. Fifth, he disregarded hospital procedures by removing emergency room directives. He also removed chairs which had been placed for visitors from the emergency room area. Finally, he failed, on one occasion, to keep the hospital informed of his whereabouts.

The Authority found that Dr. Robbins' behavior was unacceptable. The opinion states that he has shown "a continued course of conduct" which is "disruptive and abrasive." It is apparent to this Authority that Dr. Robbins has not altered his attitudes and behavior in such a manner as to permit him to work harmoniously with the other physicians and other members of the staff and administration of Liberty Memorial Hospital."

The Authority does not question Dr. Robbins' medical competence. The decision was based on his inability to function smoothly with the Staff. Although none of the seven incidents involved the defendant doctors, Dr. Robbins contends that they are the root of his problems.

II

[1] The four requisites to a grant of a preliminary injunction are "(1) a substantial likelihood that plaintiff will prevail on the merits, (2) a substantial threat that plaintiff will suffer irreparable injury if the injunction is not granted, (3) that the threatened injury to plaintiff outweighs the threatened harm the injunction may do to defendant, and (4) that granting the preliminary injunction will not disserve the public interest." None of the four factors has "a fixed quantitative value. Rather, a sliding scale is utilized, which takes into account the intensity of each in a given calculus."

Plaintiffs argue that they have satisfied the four prerequisites and that they are entitled to a preliminary injunction. Defendants contend that the hearing before the Authority was fair; that the standards applied were reasonable, and that this Court should not interfere with the decision.

III

The first issue to be decided is whether plaintiffs have demonstrated a substantial likelihood of prevailing on the merits. There is no doubt that the hearing before the Authority on November 16, 17, and 18 afforded Dr. Robbins procedural due process. He had prior notice of the hearing and of the charges. He was represented by counsel who cross-examined witnesses, presented direct testimony, and made arguments. Dr. Robbins testified in respect to each of the charges considered.

The due process issue raised appears to be that the Authority had prejudged the issue at the July 19th meeting. Its original decision that Dr. Robbins' privileges not be renewed was made at that meeting at which plaintiff was not present. He contends that the subsequent actions by the medical staff and the Authority were "filled with form but lack[ing] any substance." Implicit in this argument is the conclusion that the jury would agree and that plaintiffs would, consequently, prevail on the merits.

The Fifth Circuit has emphasized the limited role of courts in reviewing decisions of hospital boards.

> "No court should substitute its evaluation of such matters for that of the Hospital Board. It is the Board, not the court, which is charged with the responsibility of providing a competent staff of doctors. The Board has chosen to rely on the advice of its Medical Staff, and the court cannot surrogate for the Staff in executing this responsibility. Human lives are at stake, and the governing board must be given discretion in its selection so that it can have confidence in the competence and moral commitment of its staff. The evaluation of professional proficiency of doctors is best left to the specialized expertise of their peers, subject only to limited judicial surveillance. The court is charged with the narrow responsibility of assuring that the qualifications imposed by the Board are reasonably related to the operation of the hospital and fairly administered. In short, so long as staff selections are administered with fairness, geared by a rationale compatible with hospital responsibility, and unencumbered with irrelevant considerations, a court should not interfere. Courts must not attempt to take on the escutcheon of Caduceus."

Similarly, it has been held that once the district court had "determined that the judgment [of the Hospital Board] was supported by substantial evidence and was made using proper criteria, after a satisfactory hearing, on a rational basis, and without irrelevant, discriminatory and arbitrary influences, the work of the court came to an end."

The test "is not whether the agency arrived at the proper conclusion on the basis of conflicting evidence, but whether it acted arbitrarily and without regard to the facts." . . .

On the basis of the voluminous record before this Court, it cannot rule that substantial evidence is lacking to support the Authority's decision or that substantive due process was not afforded.

At the hearing before this Court, patients of the plaintiff and physicians attested to his ability as a doctor. His competence is not in issue. What is in issue is the turmoil and disruption he has brought to the Liberty County Hospital for years. Apparently he is imbued with the idea that where Dr. Robbins sits, there is the head of the table. Rules are for others, not him. The trouble with this conception is that the Hospital is a public institution, not his private domain. It is operated by the Authority, a thought which he apparently cannot tolerate.

[2] Personalities are at the heart of the problem. However, "it is entirely consistent with due process for a hospital . . . to evaluate those personal qualities of a physician that reasonably relate to his ability to function effectively within a hospital environment. A doctor's ability to work well with others, for instance, is a factor that could significantly influence the standard of care his patients received." . . . It is for the Authority

to decide whether personality differences are detrimental to the efficient operation of the hospital. This Court should not substitute its evaluation for that of the Authority.

[3] The question of whether or not the Authority considered irrelevant matters is actually one of whether the Authority was prejudiced against Dr. Robbins. As previously indicated, plaintiffs argue that the Authority prejudged the outcome of the November hearing as a result of the July meeting. Due process requires a fair hearing before an impartial tribunal. . . . However, "consideration on a previous occasion of the plaintiff's qualifications would not demonstrate such bias as to constitute a denial of due process." . . . Where a medical board has adopted an *ex parte* recommendation, the members are not disqualified from subsequently hearing evidence and ruling on the merits. . . .

Indeed, cases have been remanded to agencies for due process hearings after a determination that due process had been previously denied. Subsequent denials of hospital privileges have been upheld on appeal.

[4] To require recusal of an administrative board from deciding an issue properly before it, "[t]he record must support actual partiality of the body or individual members." In their brief, plaintiffs argue that the defendant doctors threatened they would leave the hospital if Dr. Robbins were not removed. There is no evidence in the record to support that contention. Even personal differences among the doctors would not have precluded the credentials committee or the medical staff from declining to recommend renewal of Dr. Robbins' privileges.

[5] "[T]he Fourteenth Amendment is not automatically offended despite the realistic possibility, even probability, that among the members of the medical staff there are some who harbor resentment or jealousy, and others who have formed personal evaluations in the course of experience over the years with the physician in question." The power to make decisions affecting privileges may be vested in plaintiff's peers in the absence of a showing of prejudice, and the existence of personal differences does not preclude an individual's participation. . . .

It was the Hospital Authority and not the medical staff which made the crucial decision. Dr. Robbins does not contend that the individual members of the Authority are prejudiced against him.

Plaintiffs did not request prior to the November hearing that the members of the Authority recuse themselves because of bias. In fact, counsel for plaintiffs indicated that he believed the Authority to be fair. Objections to an administrative officer because of bias may be waived if not timely asserted. "A claim of disqualifying bias or partiality on the part of a member of the judiciary or an administrative agency must be asserted promptly after knowledge of the alleged disqualification.". . .

IV

Dr. Robbins contends that the denial of his hospital privileges will effectively end his practice of medicine in Liberty County. He further contends that the Robbins Clinic cannot survive without the income generated by his use of the Hospital and plaintiffs will suffer irreparable harm if Dr. Robbins' privileges are not renewed since there is no other hospital facility in Liberty County.

> "[W]hen the potential economic loss is so great as to threaten the existence of the moving party's business, then an injunction may be granted, even though the amount of direct financial harm readily is ascertainable."
>
> "[I]mpossibility of proof [of money damages] has long been recognized as bearing upon adequacy of the legal remedy."

[6] Dr. Robbins has not demonstrated that it would be impossible to establish money damages if he is entitled to relief. In fact the record reflects the average number of patients he treats in the hospital. Any losses he may suffer can be computed from those statistics. Moreover, Dr. Robbins is not faced with loss of his medical license. He could establish his practice elsewhere, including his own Clinic. A physician does "not have absolute authority to practice medicine in the hospitals of this State.". . .

In short, plaintiffs have not demonstrated that they will suffer irreparable injury if the preliminary injunction is denied.

The final two prerequisites concern defendants' injury if the injunction is granted and consideration of the public interest.

The Authority feels that, if Dr. Robbins continues on the staff, it will suffer from the resultant discord among doctors, nurses, and administrative personnel, an injury offset by the damage Dr. Robbins will suffer if the injunction is not granted.

Dr. Robbins presented a parade of witnesses before the Authority and before this Court who testified concerning their loyalty to and faith in the physician. They want him to retain his hospital privileges. The Authority, on the other hand, deems Dr. Robbins' presence as disruptive and as detrimental to the harmonious functioning of the hospital and to the community as a whole.

[7,8] Dr. Robbins has failed to demonstrate a substantial likelihood of success on the merits or that he will suffer irreparable harm if the injunction is denied. The other factors important to the grant of a preliminary injunction are in equipoise. The grant of a preliminary injunction is not the rule, it is the exception. Although it is discretionary with the court, the moving party must satisfy the prerequisites. . . .

The plaintiffs' motion for grant of a preliminary injunction is denied.

Legal Aspects of Accreditation

WILLIAM P. ISELE, J.D.

It may seem somewhat contradictory to speak of the legal aspects of accreditation. Accreditation, after all, is a voluntary process, while the law is often seen as a compulsory one.

While it is true that accreditation is a substantially voluntary activity, whenever a person, institution or group seeks recognition and is denied it, or whenever a person, institution or group is stripped of its recognition, a potential exists for unfair, self-serving or repressive behavior. A certain measure of protection from such behavior is found in three areas of the law.

First, recognition which can place an institution in a position to better market its goods or services has been recognized as a valuable property right. Under the fifth and fourteenth amendments to the U.S. Constitution, such rights cannot be denied or withdrawn by governmental agencies or their representatives without "due process of law." Even where governmental action is not involved, i.e., where the accrediting body is purely private, courts in many jurisdictions have recognized a right of "common law fair treatment," which essentially parallels the requirements of constitutional due process.

What are these requirements? Simply stated, they are that all institutions similarly situated should have an equal opportunity to demonstrate their compliance with a clearly defined set of standards, and that they have an opportunity to appeal any adverse decision. The "right" that is recognized, then, is not a right to be accredited, but rather a right to be treated fairly and in accordance with understandable and reasonable standards. Consequently, an accrediting body must draw up its standards of accreditation with care, and must provide an avenue for review of adverse determinations.

A second legal concern relates to the fact that an educational institution operates in pursuit of a legitimate trade or business. Any conspiracy or combination which unreasonably restrains this trade risks violation of the Federal Antitrust laws. An example is found in the case of *Marjorie Webster Junior College, Inc.,* v. *Middle States Association of Colleges and Schools, Inc.,* (432 F. 2d 650, D.C. Cir. 1970, cert. den. 91 S. Ct. 367, 1970).

Marjorie Webster was a proprietary junior college which sought accreditation by the Middle States Association, a regional accrediting body of secondary and post-secondary schools. Middle States declined to consider Marjorie Webster for accreditation because of an internal policy that it would accredit only nonprofit organizations, not proprietary schools. The college sought an injunction compelling Middle States to consider it for accreditation. A federal trial court granted the injunction on the grounds that the accrediting body's policy unreasonably restrained the school's trade, namely the sale for profit of educational services. The Federal Appeals Court reversed, holding that the objectives of the accrediting body were not commercial, and any restraint was only incidental to its noncommercial purposes. This decision was handed down several years before the U.S. Supreme Court's decision in *Goldfarb* v. *Virginia State Bar. Goldfarb* made the antitrust laws applicable to professional activities that effected commercial restraints. It is therefore questionable whether the same result would be reached today. Even prior to *Goldfarb,* however, the appeals court in the *Marjorie Webster* case observed that:

> "It is possible to conceive of restrictions on accreditation that could have little other more than a commercial motive; and as such, antitrust policy would presumably be applicable."

The court hypothesized an example of accreditation being denied to an institution which purchased textbooks from a supplier who did not provide discounts to members of the accrediting body. Such activity would be in violation of the antitrust laws, the court speculated. Although absolving the Middle States Association of any wrongdoing, the appeals court warned that:

> "Even where less than complete exclusion from practice is involved, deprivation of substantial economic or professional advantages will often be sufficient to warrant judicial action."

In light of the antitrust enforcers' attention to health care provision in recent years, the accreditors of health-related programs or institutions should be particularly careful not to impose restraints which create commercial advantages for the accrediting body or its collaborators. But rather, they should direct their efforts toward maintaining a high standard of quality in the public interest.

WILLIAM P. ISELE, J.D., Assistant Director, Health Law Department, American Medical Association, Chicago, Ill.

The final area of legal concern I will address is that of confidentiality. Without detailing the sorts of data collected in the process of accreditation, suffice it to say that assurances of confidentiality must be honored. Institutions provide information and allow surveys for the purpose of demonstrating their compliance with accreditation standards. Candor and open discussion of deficiencies are necessary to this process. The privacy concerns of the institution about these data must be balanced against the public's right to be informed. After all, one major purpose of accreditation is to inform the public of which institutions have met certain minimum standards. As a general principle, the accreditation standards and the fact of an institution's accredited status should be public information. Generally, survey reports and self studies should be treated confidentially, absent a legal requirement for their disclosure, such as a court order. In this way, the purpose of public information as well as the purpose of continued improvement of the institution will be met.

Glossary

Accreditation: The process by which an agency or organization evaluates and recognizes an institution or program of study as meeting certain predetermined criteria or standards.

Certification: The process by which an agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.

Licensure: The process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected.

IMPORTANT MESSAGE TO PHYSICIANS

Edward A. Kamens, M.D., President of the Connecticut State Medical Society, brings to your attention the following letter and requests the cooperation and participation of all physicians in this worthy undertaking.

Dear Dr. Kamens:

In recent weeks my office has been made aware of a small problem that is of great concern to me. I request your help in preventing this issue from turning into a major problem in the future.

The recently enacted handicapped parking law requires that disabled persons who wish to use the special parking spaces be certified by a physician. This certification must show that the disabled person's ability to walk is "seriously and permanently impaired." After becoming certified they then receive special identification, either a license plate or card for the windshield, which permits them to park in the special spaces. Apparently there are claims that people are being certified that do not meet the criteria of the law.

I ask that when you are involved in filling out the special certification forms you keep in mind that:

1. the person's *ability to walk must be seriously impaired,* and
2. the disability must be *permanent.*

Your assistance in this matter is most appreciated.

With best wishes,

Cordially,

Ella Grasso

ELLA GRASSO
Governor

Deaconess Hospital: "No Smoking"

NANCY SEIDEMAN

Approaching the main lobby of Boston's New England Deaconess Hospital you see two colorful signs—a lighted cigarette barred within a circle. Inside the lobby and in hundreds of signs throughout the building, the same symbol is displayed, along with a smoking policy statement.

"No Smoking" became the rule throughout most of the Deaconess, a 489-bed teaching hospital affiliated with Harvard Medical School, on July 4, 1977 ("independence from dependence day"). Patients are not allowed to smoke without their physician's written permission; staff members' and employees' smoking is restricted to departmental lounges and one cafeteria section: visitors can smoke only in one area of the lobby. A special committee oversees the program.

"With the steady rise in smoking-related illnesses medical institutions need to assume a leadership role in prevention by helping smokers stop smoking," said Dr. Joseph L. Andrews, Chief of the Pulmonary Section at the Deaconess, and Chairman of its Smoking Committee.

With fewer than five percent of the nation's 7200 hospitals involved in the anti-smoking effort, the Deaconess is a model for other hospitals. David Humphrey, Target 5 coordinator for the Massachusetts Division of the American Cancer Society, called the program "the most progressive one I've seen."

Slow and Steady

Why not eliminate smoking? The hospital believes slow progress produces more lasting results.

"We decided to develop a smoking policy supportable by all hospital personnel," said Dr. Andrews. "Our secret was to make space for smokers."

Concern with smoking had been growing at the hospital since 1962 when employees and visitors were asked to smoke only in designated areas.

SMOKING POLICY

The New England Deaconess Hospital is committed to the promotion of health, which includes prevention as well as treatment of diseases.

Because smoking related illnesses comprise the largest proportion of preventable diseases, this hospital is taking an active role in the prevention of this massive waste of human resources.

Our policy strongly discourages tobacco use. Smoking is restricted to limited, specifically defined areas only. No tobacco is sold in the hospital.

Please help yourself and others. PLEASE REFRAIN FROM SMOKING while in this health care institution.

"No Smoking" in 1963

As a result of a May 1963 letter from Dr. Richard Overholt, thoracic specialist, the sale of cigarettes was prohibited; a notice asking cooperation in smoking only in certain areas was sent to staff and employees; "No Smoking" signs were posted in patients' rooms and elevators; visitors and patients were given notices asking them to comply.

In January 1975, the coffee shop off the main lobby; nurses' stations on all medical and surgical floors, including the doctors' section; two-, three- and four-bed

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NANCY SEIDEMAN, Editorial Assistant, New England Deaconess Hospital, Public Relations Department, Boston MA.

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wards and all corridors were designated as nonsmoking areas.

Smoking Committee

In April 1977, a special Smoking Policy Committee with hospital-wide representation met. Their policy went into effect on July 4.

To build support, the policy was discussed at meetings by the administration, department heads, supervisors and surgical and medical staffs. Signs were posted throughout the hospital. Information was included in all internal publications; a "Smokers Corner" column appeared in *Pulse*, the hospital's monthly newspaper. Anti-smoking literature and a large display showing the adverse effects of smoking on the body were set up in the lobby. Meetings were held with employees to get feedback. Problems of space allocations caused the most controversy.

Five months later committee member Dr. Blake Cady pointed out that smokers were visible in the lobby, so 13 percent of it was partitioned off as a smoking section.

A questionnaire found that 11 percent of physicians, 41 percent of nurses, 37 percent of employees and 36 percent of patients were smokers. Two hundred employees indicated an interest in smoking cessation clinics; one was given in November 1977.

An Evolving Program

The smoking policy is still evolving—the committee has recently eliminated smoking from the main lobby by moving the smoking section to a room directly downstairs. The Personnel Department is compiling statistics on the amount of time and money smoking employees cost the hospital. The results may make it worthwhile to hire an expert to help employees quit smoking. In the meantime, the Personnel Department may designate a health clinic employee to organize a smoking clinic and to stress the no smoking policy to new employees.

Guidelines for Success

The committee would like to prepare "how-to-do-it" packets for other hospitals, institutions and the public. Committee members also plan to establish community outreach clinics. Dr. Andrews regularly lectures on the program to many Boston area hospitals and groups, emphasizing the following points:

"The main ingredients in a successful program are:

1. Direction from a top management that is *committed* to supporting a program to reduce smoking;
2. Not only initial formulation for a comprehensive program, but effective monthly *follow-up* by representatives from all departments.
3. Continuous adjustments to drop plans that don't work;
4. Widespread publicity, so that all members of the organization are aware of both the aims and the procedures of the smoking reduction program."

Those closely involved with the committee sometimes feel frustated by what they see as slow implementation of the smoking policy's goals over the past two years. However, recent recognition from the American Cancer Society and many health care institutions, such as Cambridge City, Massachusetts General, Baptist and Union-Truesdale, which have looked to the Deaconess for guidance in setting up a policy, has given extra impetus to the program.

The Deaconess has been praised by Carol Stolberg, of the Massachusetts Regional Cancer Control Committee: "as soon as you walk in the door you know that it is an anti-smoking institution by its signs—other hospitals give no indication whatsoever on how they stand," she said.

A follow-up questionnaire answered by 965 of 2700 hospital staff members 20 months after the start of the smoking policy showed that 96 percent of nonsmokers and 83 percent of smokers approve of the smoking policy, and that 87 nonsmokers had quit during the year, 58 smokers were smoking less, and 93 had tried to quit.

Drug Usage Among Amateur Athletes

AMA BOARD OF TRUSTEES

The AMA has been asked to "establish policy dealing with the prescribing of drugs to amateur athletes, possibly along the lines of standards already established by the United States Olympic Committee."

Introduction

The use of drugs by athletes in the hope of enhancing athletic performance is not a new development. During the European six-day bicycle races of 1879, certain contestants used caffeine-based sugar cubes dipped in ether, alcohol, and nitroglycerin to improve their staying power. However, valid scientific studies have not demonstrated that the administration of any chemical substance can elicit a greater athletic performance from an individual than he is capable of by virtue of his own natural resources and natural ability; performance can only be improved through proper conditioning, dedicated training and determined effort.

"Doping" is the generic term for such an attempted increase in achievement during sporting contests through the use of any of a variety of chemicals. According to the International Olympic Committee, doping is considered to be either the use of any substance foreign to the body or of any physiological substance taken in abnormal quantity or taken by an abnormal route of entry into the body, with the sole intention of increasing in an artificial and unfair manner the performance in competition. In addition, certain psychological measures to increase the performance of an athlete in sporting contests are regarded as doping. The treatment of an illness with medication is not considered doping, although such treatment must be reported to the committee.

The alleged effects from using these substances in an athletic competition are: an increase in strength, endurance or performance; an intensified mental concentration; a diminished sense of fatigue and exhaustion; a diminished pain perception; and/or a reduction in anxiety and tremulousness. Because such "doping" does not enhance athletic performance and because of the dangers of drug abuse, the AMA has, in the past, actively sought to discourage the use of stimulants, sedatives and anabolic steroids by athletes (Resolution 89, A-72). The International Olympic Committee has also acted to put into practice some rules for monitoring Olympic events.

Current Use of Drugs in Athletics

It is difficult to determine how widespread is the use of drugs in sports for obvious reasons. So-called "doping" agents appear to be used rarely by amateur athletes. Some writers indicate that doping is extensive in certain professional sports such as football, while the authorities claim the opposite. In a 1970 study of 93 National Football League players from 13 teams, 61 percent admitted taking amphetamines regularly. At that time, the drugs were distributed by trainers and team physicians. Since the use of amphetamines was prohibited by the league in 1971, players may have searched out other sources of drugs. A study conducted in 1973 indicated that, of 87 professional football players, 48 used amphetamines regularly, 9 occasionally, and 30 players did not use drugs. Individual writings of ex-players also indicate a high frequency of use for prohibited drugs. On the other hand, these claims are denied by the league commissioners and other officials who generally indicate that a drug problem does not exist in their particular sports.

In Olympic competition, where urine testing is mandatory for selected events, only 11 of 2,080 tests were positive (0.05 percent) during the 1976 Montreal Olympic Games. One of the positive results was due to medication possibly taken in error by an athlete for an asthmatic condition. Eight positive results were due to the use of anabolic steroids.

The International Olympic Committee Standards

A very sophisticated, highly accurate, extremely expensive and time-consuming set of tests has evolved to discourage the Olympic athlete from resorting to the use of drugs in international athletic events. A random number of finishing positions to be tested are selected prior to the event by the sport-governing body in that event without the knowledge of the participants. For example, the finishing positions 1, 2, 3, 5, and 7 might be selected. Test marshals at the finishing line give the athletes who finish in these positions a card with instructions to report to the dope-testing station as soon as possible; failure to do so could result in disqualification from the event. On arrival at the testing area the contestant selects a set of two similarly numbered bottles and voids a specimen of urine (at least 50 ml) into one of the bottles (under the constant surveillance of a member of the medical commission). Half of the specimen is decanted into the second bottle and the two bottles are sealed in the presence of the athlete. One is forwarded immediately for testing; the second is refrigerated and, in the event of a positive result from the first specimen, is similarly tested in the presence of the athlete or a member of his team. The methods of testing include gas chromatography, mass spectrography, and computer interfacing.

The following drug substances are considered doping agents in sports and are sought for in tests by the medical commission of the International Olympic

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EDITOR'S NOTE: This is a report of the AMA Board of Trustees to the House of Delegates at its meeting in December 1979.

Committee. The use of these drugs is forbidden in athletic competition. Other substances may be added: e.g., at the request of the international federations concerned, the alcohol test is included for the fencing and modern pentathlon and biathlon shooting competition.

A. *Psychomotor stimulants*—Amphetamine, Benzphetamine, Cocaine, Diethylpropion, Dimethylamphetamine, Ethylamphetamine, Fencamfamine, Methylamphetamine, Methylphenidate, Norpseudoephedrine, Phendimetrazine, Phenmetrazine, Prolintane and other related compounds.

B. *Sympathomimetic amines*—Ephedrine, Methylephedrine, Methoxyphenamine, and other related compounds.

C. *Miscellaneous central nervous system stimulants*—Amiphenazole, Bemegride, Nikethamide, Pentylenetetrazol, Strychnine and other related compounds.

D. *Narcotic analgesics*—Dextromoramide, Dipipanone, Heroin, Morphine, Methadone, Pethidine and other related compounds.

E. *Anabolic steroids*—Methandienone, Nandrolonedecanoate, Nandrolone phenylpropionate, Oxymetholone, Stanozolol and other related compounds.

The following matters would have to be considered if the American Medical Association or any other body were to attempt to establish policy guidelines for prescribing drugs to amateur athletes in conformance with the standards established by the United States Olympic Committee.

1. A reliable and scientific checking system for drug use in athletics is most expensive and time consuming. The drug surveillance program for the 1976 Olympic Games involved an expenditure of over $2,000,000 for the performance of only 2,080 tests, even though this program included the volunteer services of 300 physicians and medical students.
2. Where urine is the biological fluid of choice for minitoring, facilities and staff must be available to collect duplicate samples and to label, seal and code these samples properly. One sample should be retained for possible retesting, and absolute security must be maintained over the study sample until tested in a laboratory capable of determining minute amounts of the various drugs.
3. Most laboratories are equipped only for determination of fairly large amount of drugs, such as in poisoning and suicides. Thus, a separate laboratory capability would have to be developed. Gas chromatography, electrophoresis, crystallography, and radioimmunoassay can be used for analyses of the various compounds, but these procedures require specialized and well controlled laboratory equipment.
4. If positive results for drug usage are found in any athlete, the person whose urine tested positive must be informed so that he can take his half of the specimen to a laboratory of his choice.
5. Serious medico-legal problems may arise in any drug detection program for amateur athletes, based upon the legal arguments surrounding invasion of privacy for the individual.
6. Whenever drug testing is to be considered for athletic competition, it should be done on random participants in the game or event. When only winners are tested for drug abuse, the implication arises that there may be favorable relationship between winning and drug use. The opposite has been found to be true in practice.

In view of the above requirements for scientific adequacy, sample security, legal liability and fairness to contestants, the estimated expenditure of funds for even a limited program of testing a few of the 5.7 million amateur athletes for drug use would be truly staggering. It is extremely doubtful whether adequate funding could be found for this purpose through any athletic program organized for amateurs.

The AMA will continue to support all educational efforts to curb any drug abuse in amateur and professional athletics and to cooperate fully with those amateur sports governing bodies which have already outlawed the secret use of stimulatory drugs. These groups are the International Olympic Committee, the United States Olympic Committee, the International Athletic Federation, the National Collegiate Athletic Association, and the National Federation of State High School Associations.

In its communications with the public and the profession, the AMA will stress that:

1. There is no valid scientific evidence that any drug has ever resulted in improved athletic performance.
2. Drugs of any type should be used only under strict medical supervision for the treatment of disease, deficiency or injury.
3. An athlete under medical treatment for an acute illness should not compete until restored to full health.
4. In instances where a medical condition permits competition, any drug taken chronically under medical supervision for medical reasons should not disqualify an amateur athlete, provided the athlete documents the fact in advance of the contest.
5. No injured athlete should be treated with a local anesthetic or narcotic/analgesic drug, with the object of continued competition, when the athlete might risk serious and permanent disabling injury.

The Board of Trustees recommends the adoption of this report in lieu of Resolution 97.

Month in Washington

The Senate has adopted legislation constraining the Federal Trade Commission's authority and by only two votes failed to approve an amendment specifically blocking the agency from further activities against the medical, legal, dental, veterinary and other health professions as well as their respective nonprofit associations.

On the same day, the U.S. Court of Appeals in Washington, D.C. sent back to the agency its proposal to prohibit all state restrictions on the advertising of eyeglasses and services, suggesting that the FTC may have gone too far in pre-empting states' powers.

Apparently mindful of the hostility building up in Congress, the FTC on the eve of the Senate vote refused to take any immediate action on staff proposals to limit physicians' membership on the boards of Blue Shield plans. The matter was made a proposal for public comment on what course the agency should take, including the option of no action at all.

The amendment defeated 45 to 47 on the Senate floor would have prohibited the FTC for two years from overriding state laws and pre-empting state regulations covering the legal and health professions. It would not have affected current FTC cases, including the decision to act against the American Medical Association's ethical strictures against improper advertising.

Sen. Wendell Ford (D-KY), floor manager of the Senate bill, argued against the amendment on grounds that it might jeopardize the entire measure. But he said he was sympathetic and "vigorous" hearings on the issue would be scheduled soon. Ford also said he had talked with the FTC and it had "agreed to hold off."

Sen. James McClure (R-ID), sponsor of the amendment, told the Senate that since 1976 the FTC has sought "questionable statutory jurisdiction over nonprofit professional associations by pursuing complaints against the American Dental Association, the AMA and various state and local nonprofit professional associations regarding ethical restrictions on advertising of professional services." He said the FTC proceedings have continued despite the fact that the associations have conformed their ethical codes with the Supreme Court decisions in the field.

The Senator noted that 17 state attorneys general had joined the optometric and medical professions in protesting the "eyeglass" FTC ruling.

"We believe it is time for Congress . . . to call a temporary halt to this uncontrolled misallocation of public funds, and to begin to rectify these unnecessary and unauthorized acts of the FTC by which it is attempting to substitute its 'legislation' judgment for that of the respective states and Congress."

Under a Senate amendment, approved 87-10, the House and Senate Commerce Committees would have 20 days to review an FTC rule before it could take effect. If either committee objected, both House and Senate would have to agree within 60 days with the President concurring for the rule to be invalidated.

The House FTC bill would allow either House or Senate to reject an FTC trade rule within 60 days, the so-called one house vote.

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Sen. Richard Schweiker (R-PA) has introduced a comprehensive health manpower bill that would eliminate capitation aid to medical schools and sharply scale down the size of the National Health Service Corps.

Aid would be provided students, but the bill "while recognizing the high cost of training, signals an end to the free ride," Schweiker said. "I believe we should continue student aid because otherwise the health professions would be only for the very rich."

Schweiker, top Republican on the Senate Human Resources Subcommittee on Health, said his bill aims at fiscal constraint and use of inducement rather than regulation.

The bill would establish a new student loan program, utilizing existing private loan markets, which would provide modest interest subsidies while the student is in school, but would go to a market-rate loan once the student was in practice. Also provided would be increased availability of loan forgiveness inducements for health professionals who practice in medically underserved areas.

Expanded special projects grants would assist schools in carrying out programs designed to improve the geographic and specialty distribution of health professionals and to strengthen curriculum offerings in key areas.

A new program of grants would be established to allow states to provide service scholarship programs, "thus involving states in solving geographic distribution problems."

A new financial distress grant program would be keyed to state and local support for schools with long-term financial problems.

Schweiker said capitation grants "have served useful purposes in the past, but do not now adequately assure that institutions receiving the grants act in the national interest and thus deserve support. We are in a time in which all Americans must restrain the demands they

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Prepared by the Washington, D.C.
Office of the American Medical Association

place upon the federal budget. In these circumstances, capitation is a luxury we cannot afford."

Another policy change in the proposed legislation would phase down, over a two year period, the National Health Service Corps scholarship program to about one-third of its fiscal year 1980 level. "This program has, rather unfortunately I think, been expanded because of the demand for scholarship money for health professions students, rather than by a responsible assessment of the actual need for health professionals in nonmilitary service in 1985 and beyond," Schweiker said.

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The American Hospital Association has approved a policy statement that hospital medical staffs should set up standards for people who perform health services but are neither hospital employees or members of the medical staff.

"It is essential that the appropriateness of their service or scope of activities within the institution as well as the qualifications of these individuals be evaluated by the hospital," said the AHA during its annual meeting in Washington, D.C.

The AHA said medical staff bylaws should establish procedures for:

- determination of the general qualifications to be required of the non-staff employee practitioners and level of medical supervisions needed.
- recommendations regarding the scope of activities for each practitioner, determined on the basis of an assessment of qualifications such as educational background, licensure, certification, experience, and demonstrated current competence.
- recommendations regarding categories for appointment, performance review procedure, reappointments, disciplinary actions, and appeals procedure.

The AHA said hospital procedures should specify that the activities of the practitioners in question are to be performed in consultation with the medical staff and that they (procedures) will not be undertaken unless either (a) requested or approved by admitting or attending physicians, or (b) indicated in a protocol developed or approved by the medical staffs, and consented to by the patients.

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The Department of Health, Education and Welfare has announced a national study of the use, costs and financing of health care services in the U.S. A joint project of the National Center for Health Statistics and Health Care Financing Administration, the study will involve 10,000 households across the country. It will produce detailed information on the amounts and types of health care received during 1980, the costs of the services and the sources which helped to pay the bills. The information will be used to measure and monitor the effects of existing health care financing programs on health status and costs.

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A telephone-book size directory of Northern Virginia physicians, the most detailed directory of its type in the nation, has been published by the Health Systems Agency of the area. About half the practicing physicians submitted information for the directory which has a cover picture of a physician holding a stethoscope to a youngster's chest.

Five thousand copies of the 441-page directory were printed at a cost of $25,000 to the Health Systems Agency of Northern Virginia. They will be furnished at no cost to the public. Several other Health Systems Agencies (HSAs) have also produced directories. About 36 directories of physicians have been published by various groups, including medical societies, in recent years.

The Virginia directory includes information on physicians' policies on accepting Medicaid and Medicare patients, fees for standard office visits and tests, policies on billing and insurance, office accessibility for the handicapped, and prescribing by generic name.

Information is also listed on education, certification, hospital affiliations, office hours, usual advance notice required for appointments, types of laboratory tests available in the office, foreign languages and sign language spoken by the doctor or staff, and mechanisms for handling patient inquiries and complaints about billing.

The directory presents information about the Health Maintenance Organizations providing health care services in Northern Virginia, and a summary of the services provided by area public health departments.

The medical societies in Arlington, Fairfax and Prince William counties helped participate in the project.

Publication of the directory was halted in order to challenge the constitutionality of the Virginia Medical Practices Act that had prohibited physicians from furnishing information for the directory. The statute was found to be unconstitutional in November, 1976.

The President's Page

Pain and Suffering—What Price?

The other day a resident physician at a hospital conference raised a troublesome contemporary issue. "Why," he asked, "if in any patient the diagnosis of a solid mass in the body or tail of the pancreas was established by CAT scan should anyone be prompted to pursue further investigation?" He reasoned further that if the diagnosis was that of a malignancy the outcome was inevitably bad, and if the process was benign one could then await further developments that might or might not indicate further intervention. This seemed to him a more "cost effective" approach to the management of this problem. Cost effectiveness is a subject of major consideration in medical education these days.

Now, I can't quarrel with the concept of opposition to wasteful, inefficient and reduplicative management of health care problems, but I do bristle when humane factors are left out of either the cost-effective or the cost-benefit equation. I also understand the difficulties faced by academicians who try to integrate pain and suffering into some formula that would lead to a solution of our economic problems in a more equitable fashion. The problem, however, is that although they are cognizant of the factors "pain and suffering," they cannot assign a value to them so they then dismiss them from the formula and further discussion, until, of course, an expert appears as a witness in a litigation where "pain and suffering" suddenly transmogrify into indefinable terms but always into very large numbers.

Medical schools and hospitals today exert great pressure on staff members to teach cost containment methodology to physicians, wherein, in dollars and cents terms, "pain and suffering" have been relegated to a nether world. These two wraiths come back to haunt us, however, as apparitions of speech in the lecture halls and at bedsides in the ICU's. Fortunately, eons ago when I went to medical school "pain and suffering" were not phantoms in a formulary but concrete factors in the careful, thoughtful and sensitive delivery of health care to our patients.

Third party carriers, in those days, were still in their infancy without significant growth and development and had not yet matured into the adult world of conglomerates that delve into banking profits, consulting and research projects, and HMO ownership. It was also before "pain and suffering" were politicized by ambitious office seekers who legislated massive injections of federal funds into unrestricted hospital expansion and unlimited utilization of the health care systems so that these latter two became the most visible components of an inflationary spiral of health care costs. In that bygone era intellect, integrity, skill and quality were considered far more worthy of compensation than quantity of procedures. Oh those halcyon days!

Lest I be misunderstood, however, let me emphasize that I in no way am implying a criticism of technological advance in medicine. On the contrary, a recent Robert Wood Johnson Foundation study concretely *refuted* the contention of some health planning agencies that the high cost of technology was primarily responsible for the high cost of health care. The study showed that if one were to destroy one-half of all of our high technology, the immediate impact would be less than 1% on the cost of health care in this country. The study conclusively showed that it wasn't technology or quality care that caused health care costs to soar into the stratosphere, but rather the frequency of testing procedures that had nickel and dimed us into bankruptcy!

We physicians must not permit the farce and hypocrisy of allowing others to claim amelioration of "pain and suffering" as the rationale for screening from scrutiny the real culprits in health care costs namely: 1) review organizations that propose more expanded standards of review 2) expanded litigation, malpractice suits and defensive medicine, and finally 3) preventive care expanded into bigger more massive screening programs that are wasteful, inflationary and unnecessary.

In my opinion, the way to reverse this trend is to place a premium on the qualities Hippocrates immortalized and to which we all gave lip service. By adhering to these simple, humane qualities we not only will have alleviated a great deal of the "pain and suffering" our patients endure but also, in a figurative sense, that which we all feel in our pocketbooks.

Edward A. Kamens, M.D.
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Reflections from the Dean's Office

The Best Laid Plans

ROBERT U. MASSEY, M.D.

There is a school of philosophical thought called epiphenomenalism which teaches that *mind* arises from the activity of matter—the brain or central nervous system—but is in itself the cause of nothing. All of that mental activity of which we are daily aware is like smoke rising from a fire, having no retrograde effect either upon our brains or upon the rest of the material world. We do what we do because that is the way our organisms work; what we think or feel about all of that is of no consequence. So much for epiphenomenalism.

There is an analogy in the real world. In the day-to-day care of patients, we do what we do because that is the way doctors work. Our science is better, our technology is ingenious, but the purpose of our work is the same now as it has been for centuries: to cure sometimes, to relieve often, to comfort always.

Alongside this activity, there are epiphenomena rising like smoke and, like smoke, often irritating. One of these epiphenomena is the busyness of health planning and regulation, all of the pronouncements about crises, non-systems, costs, failure of market forces, maldistribution, and inappropriate services. All are proper concerns for physicians, patients, hospital administrators, and medical school deans.

All the while, however, the death rate is falling, some incurable leukemias are cured, crippling angina is eliminated, and everyday thousands of trivial and not-so-trivial illnesses and discomforts are cared for and relieved. Most of this work is carried on by men and women who know little about the beehive activity of the planners and regulators and, in fact, are indifferent toward it. Planning and regulation mostly qualify as epiphenomena, providing jobs, diverting resources, but changing little and profiting less.

Surely before Plato there were utopians, those who believed that society should be planned, that they should be the planners, and that then everyone should be held to the plan by regulation or repression. Historically, utopias have either collapsed early because of flaws in their conception or persisted on to their natural end, which is tyranny.

But planning has a place in our world; our minds are repelled by the notion that we either cannot or should not chart our destinies, invent our futures. If plans were no more than epiphenomena, mere smoking rising from human activity, it would make no difference whether we schemed and planned or not; if they were only dreams, forgotten upon waking, we shouldn't worry.

But planning is clearly more than dreaming, more than smoke or noise, more than an epiphenomenon. It does affect the real world, and Osler's advice to live our lives in day tight compartments cannot be applied to every person in every day.

The idea of planning gets caught up in the concept of liberty. If we plan for ourselves, we are free to change those plans; if we plan as a group, we run the risk of having those plans imposed; if a whole society plans, or is planned for, there is danger that plans cannot be changed even though to persist in them means destruction. Plans are decisions about the future before all the circumstances can be known. If they are only my plans, change is easy and cheap; if they are collective plans, they had best be right because change will be costly.

Health planners excuse their ineffectiveness and errors with the remark that the "science" of health planning is in its infancy. It seems to me that planning can only be right by chance because we can never know enough.

The errors of planning should be expected and should be subjected to continuing correction; planning, which is merely deciding things ahead of time, should be done mostly by those who have the responsibility and who will be held to account. The planners and regulators will be forgotten tomorrow; if American medicine is third rate in 1990, they will not be around to blame.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Physicians' Obligations to Maintain Privacy and Confidentiality I: General Considerations

JOSEPH M. HEALEY, J.D.

Among the many perplexing issues facing contemporary practitioners of medicine is the uncertainty surrounding their obligations to disclose or to refain from disclosing personal information obtained during the physician-patient relationship. The problem is not, of course, a new problem, but a number of recent controversies such as the medical treatment of the Shah, public interest in the health of presidential candidates, and the high incidence of child abuse, spouse abuse and abuse of the elderly, force us to view the problem in light of current reality. In a society such as ours, there is always a danger that either of two extremes will prevail: that any withholding of information will be construed as evidence of wrong-doing and conspiracy and is unacceptable; or that any disclosure will be construed as a violation of patient rights regardless of the circumstances. As in so many areas of the contemporary law-medicine relationship, a sense of balance and perspective is indispensable.

There is a long and distinguished ethical tradition in medicine which considers information communicated to physicians in the course of a physician-patient relationship to be sensitive and entitled to protection. This tradition extends from the original formulation of the Hippocratic Oath to the present-day Principles of Medical Ethics of the American Medical Association. The right to expect that such information will not be disclosed to third parties is a right which belongs to the patient. Though an important right, it is not an absolute right. The extent to which it is a legally enforceable right for the patient depends upon three things: the extent to which the jurisdiction involved (usually a state) has given the right legal protection, the circumstances and the purposes of the proposed disclosure and the acceptance or rejection of disclosure by the patient. Though disclosure may be generally prohibited and actionable by the patient if it occurs, either the consent of the patient or the existence of a legally compelling justification may be the basis for disclosure without legal liability. A number of such situations exist. Though disclosure of a patient's medical history to a third party may be generally a source of potential liability, disclosure to an insurance company at the request of a patient is required and not actionable. Though disclosure of the patient's diagnosis without consent could be generally actionable, those statutes which require reporting of certain diseases make such disclosures to appropriate health authorities not only permissible but usually mandatory. The general principle of confidentiality supports protection of the patient's expectation of non-disclosure yet permits disclosure when requested by the patient or required by either state statute or the laws governing the admission of medical evidence in the legal process.

The legal concept of privacy has evolved from a general concern for the right to be left alone to the status of a constitutionally-based protection of the exercise of choice in certain health care contexts (especially reproductive decision-making). Much like confidentiality, privacy is not an absolute right but must be viewed in context. There exist both practical concerns and legitimate state interests which justify limitations on its exercise. It has emerged as a major factor in such diverse contexts as the Quinlan case, the abortion issue, criminal prohibitions against homosexual activity, the psychiatric patient's right to refuse treatment, and the terminally ill patient's right to use laetrile. Though this right does not have either the long history or statutory commitment which the right of confidentiality does, it remains an important and valuable force in the contemporary physician-patient relationship.

In the next two columns, I will outline some recent cases addressing the rights of confidentiality and privacy and explore their influence upon the three controversies raised earlier in this column.

JOSEPH M. HEALEY, J.D., Assistant Professor of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington, CT.

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EDITORIALS

Lead Poisoning—The Precedents of Micro-Assay

This month's issue of *Connecticut Medicine* contains an article entitled "Micro-determination of Blood Lead," which adds to the long and distinguished list of literature on the subject of lead poisoning. Although the syndrome was first clearly delineated thirteen centuries ago by the eclectic Greek physician, Paul of Aegina, a forebear from the days of classical antiquity had already described the symptom-complex in verse. Nikander of Colophon, a physician-priest of Apollo, had written in the second century before Christ of:

The harmful cerusa, that most noxious thing*
Which foams like the milk in the earliest spring.

The poet went on to versify of the progression to colic, ocular symptoms and paralysis, concluding on the final grim note:

His strength is now spent, and unless one soon aids
The sick man descends to the Stygian shades.

Important contributions to the clinical description and epidemiology of lead poisoning were made during the 18th century. The disease known variously as Colica Pictonum in northern Europe, Devonshire Colic in England, and West-India Dry-Gripes in America was eventually shown to be caused by drinking lead-contaminated liquids: the Colica was due to the ingestion of water stored in cisterns that collected rain dripping off leaden roofs, the Colic originated from lead-lined cider presses, and the Dry-Gripes came from the lead stillheads and worms used in the distilleries of the New World's rum industry.

Of all of the 18th century additions to our understanding of plumbism, the most fascinating by far is that of the genius of the colonies, Benjamin Franklin. The problem of lead poisoning had first entered Franklin's consciousness when he was a youth of 17, in Boston. Because some North Carolina consumers of New England rum were complaining that the Yankee product was causing "dry belly-ache and the loss of the use of their limbs," a few Boston physicians conjectured that the lead in the distilling equipment was at fault, and persuaded the Massachusetts legislature to pass, on July 31, 1723, an act prohibiting its use.

The following year, while learning the printer's trade in London, the young Franklin again had the opportunity of observing the noxious effects of lead, this time on workmen who were careless in handling metallic type. Some years later, he pointed out the dangers to Dr. George Baker, a Devon physician who achieved fame and a knighthood in 1767 by proving that Devonshire Colic was caused by the leadlined cider presses used by the farmers in his native county.

And so it was more than fortuitous that the Philadelphia physician, Thomas Cadwalader, should bring to Franklin's printing establishment a manuscript he wished to have published entitled, "An Essay on the West-India Dry-Gripes." Cadwalader's study gave further support to Franklin's contention that the disease was caused by the lead in the rum-distilling equipment, and substantiated the observations the printer had made in his youth. Thus was brought forth in 1745, by the printing presses of Benjamin Franklin, what is now recognized as the first medical monograph published in America.

One further reflection—over the past 150 years significant advances in American medical science have been made by members of the Meigs family in Philadelphia, Boston and New Haven. Considering the light that has been thrown on the problem of lead poisoning in two of those cities, *Connecticut Medicine* finds a certain historical symmetry in the fact that the senior contributor to this most recent advance is J. Wister Meigs of New Haven.

Sherwin B. Nuland, M.D.

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* A lead-based white cosmetic or paint.

The Chronic Offender and Hospital Privileges

Included in this issue is the case of Dr. Robbins v. his Medical Staff and Hospital concerning nonrenewal of his privileges, decided by a Georgia federal court. It deals with the chronic offender, a problem that is finally surfacing to the point where medical staffs and hospital administrations are recognizing it as needing remedial action, though difficult to handle. It has recently reached the courts. This is why this case is important to study; it presents a model of excellent procedure for a difficult and important problem that may be seen more frequently.

The actions of the chronic offender can be related to his competence or to his personality, causing questionable incidents which individually or occasionally present no problem, but repeated over a relatively short time call for some sort of corrective action by his colleagues. Judgment is required to define the line between the occasional slip and the repetition or habit that requires action. In this case, the professional competence of Dr. Robbins was not the issue; it was his personality and behavior.

The medical staff, the lay Hospital Authority, and the courts in denial of his reappointment held that his personality and behavior were so abrasive and disruptive to those with whom he came into contact that the hospital could not "offer to the public that quality of care which the public has a right to demand."

When his reappointment was denied, the doctor sued the medical staff and hospital, accusing them of denial of due process and of conspiracy and restraint of trade. The court decided against him on all counts. The procedural due process followed by the medical staff and hospital, approved by the court, provides an excellent model. I know of no case in which the courts have overruled a hospital decision on substantive medical issues where a physician has been given a fair hearing as understood by fair-minded physicians and lay people. The courts do not insist on the legal standards of the courtroom in such cases. The procedure in this case can just as well be used for the chronic offender in professional competence also.

As for the charge of denial of due process, the court noted that he had had "prior notice of the hearing and of the charges. He was represented by counsel, who cross-examined witnesses, presented direct testimony, and made arguments. Dr. Robbins testified in respect to each of the charges considered." But the staff and hospital gave him more. Necessary for this type of case, he was given a written list of incidents that occurred over a period of months, with the opportunity to discuss each one. His conduct was reviewed by the medical Credentials Committee which recommended nonrenewal of his privileges; it was next discussed, voted on, and upheld by the entire medical staff. The lay Board even denied the initial recommendation of the medical staff to deny his privileges; instead, it put him on probationary notice. Finally, on his appeal to the Board from the medical staff recommendation, it gave him a 3-day hearing, with a transcript nearly 800 pages long.

The substantive issue was behavior and personality. The court followed the prevailing legal principle: It would not substitute its judgment for that of the medical staff and hospital: "No court should substitute its evaluation of such matters for that of the Hospital Board. It is the Board, not the court, which is charged with the responsibility of providing a competent staff of doctors. The Board has chosen to rely on the advice of its Medical Staff, and the court cannot surrogate for the Staff in executing this responsibility."

Few medical staff bylaws include written procedure that deals with the chronic offender. There should be. Some hospitals are now keeping dossiers on physicians, not always made known to the medical staff or to involved physicians. At least two factors are contributing to this practice. For some years, especially since the landmark Darling case, hospital administrations and boards of trustees are taking more seriously their legal and ethical duty and responsibility to monitor medical care in the hospital including that given by each physician to insure a high standard of care. Also, nurses believe they have a greater responsibility and ability to care for patients, even though the patient "belongs" to a physician. They are being taught to assume a greater role in the total care of patients, questioning physicians' orders and management of patients. They are also reacting to the climate of malpractice. Because of the hierarchical structure in hospitals, a nurse reports any incident to her supervisor, and up the scale to the chief nurse, to the hospital administrator and/or the president of the medical staff and chief of the particular service involved.

How a single or series of incidents reported in such fashion should be handled is a question each staff should resolve, and formalize in writing in bylaws. Fairness compels that a physician should know what is in his file and have the opportunity to answer it. The time has come for medical staffs to recognize and deal formally with the chronic offender even though it is a difficult problem.

Fred Fabro, M.D.

The Chronic Offender

A hospital acted properly in disapproving a physician's application for reappointment to the hospital's medical staff, an Illinois appellate court has ruled.

The physician's application for reappointment had been denied without a hearing by the hospital board of directors. A trial court enjoined the hospital from prohibiting the physician from practicing until a proper hearing was conducted to determine his eligibility to practice there. Subsequently, the physician was provided with notice of a hearing and 16 general charges, supported by 21 separate incidents.

The medical staff executive committee, sitting as a credentials committee, conducted the hearing. The committee found several instances where the physician had made disparaging remarks to or about personnel, two instances where he failed to respond to requests for assistance, and two instances of improper care of patients. The committee recommended denial of privileges. In various appeals, the hospital's joint conference committee, the full medical staff and the board of directors affirmed this recommendation. The trial court upheld the Board's action and the physician appealed.

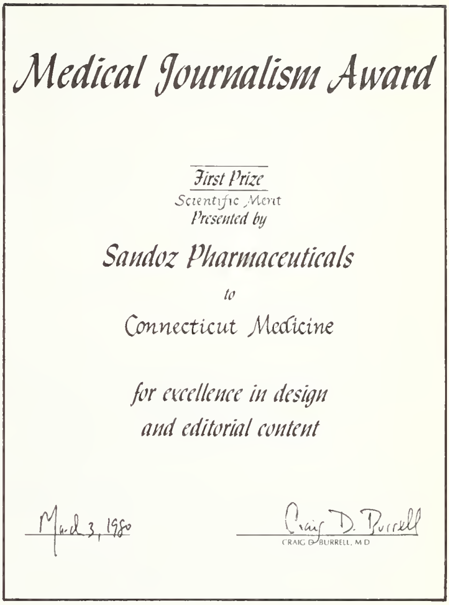
The first issue the physician raised was the alleged bias of one of the three members of the executive/credentials committee. That member had assisted the hospital attorney in preparing the charges by interpreting a memorandum from the director of nurses. Due process does not require that every member of a panel be completely unfamiliar with the facts of a case, the court said.

The physician had been given notice of the charges, and had a hearing before an impartial tribunal, was represented by counsel, and had an opportunity to cross examine witnesses, present evidence and inspect documents, the court found. Furthermore, no member of the executive/credentials committee was a member of the board of directors which made the final decision, the court added.

The physician also objected to the hospital attorney's dual role as "prosecutor" and advisor to the board of directors. The attorney may acceptably present evidence and advise the board, so long as he is not a member of the board, the court said.

Finally, the physician challenged the committee's findings with respect to the instances of allegedly improper care of patients. These findings were not supported by substantial medical testimony, the appellate court agreed. Nevertheless, the physician's inability to work with other members of the hospital staff was supported by ample evidence, and was in itself sufficient grounds to deny the physician staff privileges, the court concluded.—*Ladenheim v. Union County Hospital District,* 394 N.E. 2d 770 (Ill. App. Ct., Aug. 29, 1979)—THE CITATION, Vol. 40, No. 8, February 1, 1980.

A Prize for *Connecticut Medicine*
The 1980 Sandoz Award



Medical Journalism Award

First Prize
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Connecticut Medicine

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and editorial content

March 3, 1980

Craig D. Burrell
CRAIG D. BURRELL, M.D.

Letters to the Editor

PSEUDOMEMBRANOUS COLITIS

To The Editor: The article published in the January issue of *Connecticut Medicine* by Dr. Daniel C. Ellison and colleagues regarding the surgical treatment of pseudomembranous colitis[1] fails to focus on the most important issue, that is, inappropriate medical treatment of pseudomembranous colitis may lead to patient demise, or the need for surgical intervention. Neither case presented received appropriate medical management. The first patient was treated for 7 days with "antibiotics" which clearly perpetuated the disease. The second patient was treated with antiperistaltic drugs, which have been shown both to precipitate and exacerbate pseudomembranous colitis. The positive blood cultures for *Clostridium paraputrificum* are of uncertain significance, but it should not be implied that these organisms were responsible for the colitis unless they have been shown to produce cytopathic toxin.[2]

Our knowledge of the etiology of pseudomembranous colitis has come a long way due to the work of Bartlett[3] and Fekety.[4] The principles of management are clear and include consideration of the appropriate diagnosis, withdrawal of the offending antibiotic, the discontinuance of all antiperistaltic drugs, oral vancomycin, intravenous fluids, and other cardiovascular support measures. The role of steroids or cholestyramine are still uncertain. With these principles, medical therapy will usually be effective and death and colectomy are avoidable.

Michael F. Parry, M.D.
Director of Infectious Diseases

The Stamford Hospital

1. Ellison DC, Dragon RE, Livingston WT. Toffolon EP, Smith CA: Surgical Success with the Medical Failure of Psuedomembranous Colitis Treatment. Connecticut Medicine 44:10, 1980
2. Bartlett JG, Chang TW, Gurwith M, et al: Antibiotic-Associated Pseudomembranous Colitis due to Toxin-Producing Clostridia. New Engl Med 298:531, 1978
3. Bartlett JG, Gorbach SL: Pseudomembranous Colitis (Antibiotic-associated colitis). Adv Intern Med 22:455, 1977
4. Fekety R, Silva J, Toshniwal R, et al: Antibiotic-Associated Colitis: Effects of Antibiotics on *Clostridium difficile* and the Disease in Hamsters. Rev Infect Dis 1:386, 1979

The above letter was referred to Dr. Ellison and colleagues who offer the following reply:

To the Editor: In response to the letter of Dr. Parry, several points must be made:

1. Our two patients had Pseudomembranous colitis but did not have *Antibiotic-associated* pseudomembranous colitis.Case #2 had not received any antibiotics prior to admission. Case #1 had received Erythromycin 6 weeks prior to admission.
2. Case #1 was admitted in July 1977. Case #2 was admitted in March 1978. The fact that Claustridia difficile toxin caused antibiotic associated pseudomembranous colitis was published in March 1978.[1] The fact that oral Vancomycin may be beneficial in humans with antibiotic associated pseudomembranous colitis was published in July 1978.[2]
3. Both cases received appropriate medical management as it was known at that time. In 1980 both patients would have probably received a trial of oral Vancomycin despite the fact that they did not have antibiotic-associated pseudomembranous colitis.
4. Our conclusion clearly states that surgery be reserved for patients who do not respond to optimum medical management. In this situation the results of surgery can be dramatic as well as life saving.

Edward P. Toffolon, M.D.
and
Robert E. Dragon, M.D.

New Britain General Hospital
New Britain, CT

1. Bartlett JG, Chang TW, et al: Antibiotic associated pseudomembranous colitis due to toxin producing claustridia. New England J Med Vol. 298:531, 1978
2. Tedesco F, Bartlett JG, et al: Oral Vancomycin for antibiotic associated pseudomembranous colitis. Lancet 2:226, 1978

PHYSICIANS AND THE LAW

To the Editor: "Colossal brass" labels the presumption of a lawyer-client combine that denigrates a doctor with punitive litigation yet later reaches toward him for cooperation to initiate further litigation in another direction. Also, the noble legal ethic of heartily defending every accused client because he could be innocent has been shifted to another purpose of pursuing the "client's best interest" with the opportunities that have arisen in litigation for profit.

Insurance funds are gathered to stabilize civilized society by relieving the burden of catastrophe when the every day risks of life meet with accident; but these funds are treated like gold mines by legal entrepreneurs. That results in diminished insurance availability with a vulnerability to pauperization for some who do not obtain insurance.

One way to eliminate all risk is to do nothing. But doctors do not have a choice to refuse treatment to patients because the risks of responsibility may be high. A legal technology for fault-finding and the exaggerated emotionality that can be aroused from the grief that naturally accompanies the normal circumstances of disease and death are utilized in litigation. The civilized demeanor of a controlled "upper lip" that distinguishes the quiet human from the loud beast changes to a wailing and whining for lucre.

There could well be "a second opinion" to advise doctors who consent to become plaintiffs' witnesses. The astronomical punitive court awards in malpractice litigation makes impossible any plans for reducing hospital or medical costs. The enrichment of trial-lawyer entrepreneurs have caused a dislocation of economic balance in a free world, and this problem may shift our freedom to authoritarianism before a solution is found.

The cancer of litigious enterprise is now epidemic. It is destroying the function of the marketplace for supporting the quality of life. The legal profession designed a Good Samaritan law so that doctors reaching a highway accident would stop and try to save life or limb. It is time for them to review the prevailing contingent fee practices and see to what extent that has become outright champerty and a danger to the liberties of all of us. The medical profession could seriously invite such attention since there are predictions of another malpractice litigation crisis.

Sidney Vernon, M.D.

Willimantic, CT

THE NEW HAVEN FOUNDATION—MORE

To The Editor: I did not realize my previous brief letter to *Connecticut Medicine* would be the object of a defensive essay. I request that I be allowed to present, more fully, our position in support of free access by patients to the physician of their choice.

The participating physicians of the New Haven Foundation for Medical Care (FMC) joined on the promise and with a contract that guaranteed "free choice for patient and physician." Instead, the administration of the FMC has arbitrarily changed the rules and has set up a system in which the primary care physician is the triage officer, the point of access, the medical Czar who limits access to, and utilization of, medical services. Free access to specialists is denied.

Several members of the Board of the FMC denied knowing of this policy when I spoke to them in November; it was instituted by the Executive Board or the Director. The FMC did not have the gumption to inform the physicians of their change in policy; they first told it, incidentally, to their subscribers in a newsletter and only later told the physicians after I complained.

There are numerous difficulties with this policy. It is an infringement of our agreement and contract. There is no evidence that limiting access through this primary care physician, provides better medicine. It probably provides for poor medicine. Note that most of the great medical institutions in the USA function by direct and free access to specialists—Massachusetts General, Mayo, Yale, Johns Hopkins. Most of the great medical schools don't even have a place for primary care—family practice medicine. A literate, informed patient with severe contact dermatitis knows he will be better treated by a Dermatologist; or a patient with an injured ankle by an Orthopedic surgeon. Most patients are smart enough to self refer. I submit the main reason for the denial of free access is cost containment—not better care.

I do not say that triage via the primary care physician is bad but when it is the only way of access to specialist medicine then it is only a device to limit medical costs and ration medical services. It leads to mediocrity and poor medicine.

The FMC will create a divisiveness in local medical practice—the specialists versus the primary care physician. If his practice diminishes, the primary care physician will delay or deny referrals in order to preserve his share of the available dollars. It may cause a return to older methods of courting referrals such as surgeons entertaining G.P.'s, etc.

The administration states that they must confine and reduce costs even if the traditional practice of medicine is to be disrupted. The administration puts responsibility on HEW. HEW states that it would like a program which limits costs and rations services but they don't care how it is done. HEW does not mandate that free and direct access be denied. They suggest we fight it out among ourselves.

I presented the case for free access to the Board of the FMC in November. Many of the Board members were ignorant of administration policies. We felt that the FMC was run by its administration rather than its Board.

The administration wants the FMC to survive even if it interferes with free choice and traditional patterns of access. Yet we joined this HMO because we were promised that the traditional way of practice would be preserved. We did not join a closed panel HMO. We joined an "IPA" run for and by County members. We are being railroaded.

At the same time, the promotional literature to subscribers suggests that traditional practice will be preserved and suggests little or nothing of the limitation of direct access to specialists. The patients are also being misled.

The denying of free access will be carried out by requiring a written authorization voucher to be picked up, prior to consultation, at the office of the primary care physician. In other IPA's, the *voucher* specifies only one visit and the patient must be returned to the primary care physician for therapy. Therapy is often as specialized as diagnosis and not to be taught by a letter. We will have medicine by voucher similar to the old welfare system of "prior authorization" which was so demeaning.

There are all sorts of potential conflicts. If a non FMC internist sends a patient to a FMC surgeon, the service is not covered. If an existing patient comes to a specialist with a different problem than before, the service is not covered. We will spend our days phoning and manipulating FMC claims.

A conflict of interest exists as the Executive Director of the FMC is also the Executive Director of the New Haven County Medical Society. It is difficult to organize an open discussion.

We have asked the administration of the FMC to call a meeting of all physicians to discuss this issue. They have so far refused.

I have asked the administration to poll the participating physicians as to their feelings on direct access. They refuse. They do not believe the physician is smart enough to make a wise choice but must be "guided" by a wise administration.

I do not represent an isolated specialty seeking to redress but rather include many of Orthopedics, ENT, Allergy, Dermatology, General Surgery, Thoracic Surgery, and Ophthalmology. The primary care physicians to whom I have spoken are also against limited access.

In the end, the patient will suffer. The FMC will deliver cost dictated mediocre medicine and not the sophisticated specialty oriented practice that America is famous for.

Ronald C. Savin, M.D.

New Haven, CT

The above letter was referred to Dr. Arnold who offers the following reply:

To The Editor: We thank you for the opportunity to respond to Dr. Ronald Savin's letter to the editor, and to clarify some misconceptions about the position of the Board of Directors, the majority of participating physicians, and the administration of the New Haven County Foundation for Medical Care (FMC).

In the past month an IPA called Choice Care failed in Colorado. We learned from speaking with participating physicians, staff, and the program's actuary, that few or no controls were established to monitor the quality and cost of medical care. The plan had no risk sharing, peer review or referral programs. The utilization experience of some specialty groups was triple that of the national average. Patients conceiving a need for medical care freely used and abused the services of specialists through self-referral. Participating physicians readily admitted that the Board and administration of the HMO were remiss in their obligation to make the physicians aware of the kinds of controls necessary to make the program a success. They further admitted that they did not take their roles in the IPA seriously, and this combination led to the insolvency of the program.

The Board of Directors of FMC, which has a broad representation of physicians from many specialties, established the referral policy in October 1977. The Board has invited all specialty groups to present their views, and in many cases has commissioned consultants to perform in-depth studies so that objective and prudent decisions could be made. Dr. Savin is incorrect when he states that many members of the Board were unaware of this policy. FMC has and will continue to make participating physicians aware of policy decisions. FMC has helped its participating physicians in the incorporation of an IPA. It will continue to work with the IPA to resolve problems of concern to both organizations.

FMC disagrees with Dr. Savin's statement that patients should make medical decisions. Doctors should make medical decisions. We agree with Dr. Savin that prohibiting self-diagnosis and self-referral by patients can result in cost containment, but disagree that this will result in the rationing of medical care. Our comprehensive benefit program covers all physician services, which are readily available to the patient when a need is documented. Subscribers are well informed of the rules and regulations of the program in writing, and are not "misled" as Dr. Savin has suggested.

FMC strongly disagrees with Dr. Savin that primary care physicians will subvert accepted medical practice and fail to refer to an appropriate specialist "to preserve his share of the available dollars." FMC cannot be responsible for other programs, to which Dr. Savin refers, that allow only one visit to a specialist. The FMC program does not specify a number of visits allowed for a course of treatment. Furthermore, the policy is flexible, allowing for patients who have visited their primary care physician within the past year to be referred by telephone. FMC will reimburse the primary care physician for the short time it takes a staff person to forward the referral form. Our policy does indicate that primary care physicians must refer to FMC participating specialists, unless such a specialist is not available amongst the 570 participating physicians. Non-participating physicians are neither committed to the concept of the program, nor involved in the risk sharing undertaken by participating physicians.

The primary objective of FMC is to preserve the private practice of medicine. The Executive Director of the program implements the policies of the Board. He has been a staunch supporter of the private practice of medicine, and has represented this interest on national, state and local levels. He has in no way hindered open discussion, but rather has encouraged discussion of all issues within the Medical Association and FMC.

It is untrue that FMC has refused to meet with Dr. Savin and the participating Dermatologists. The FMC Board met with them in November 1979, and Dr. Arnold, the President, and Dr. Tierney, the Medical Director, have offered to meet with them since that time. FMC will also be informing participating physicians of an annual meeting to take place April 9, 1980. In early March FMC will send a questionnaire to participating physicians, explaining the program and the federal qualification process, as it did in January 1979. FMC will ask for comments and recommendations at that time.

If FMC is successful the physicians and their patients will be the real winners.

Philip B. Arnold, M.D.
President

James W. Tierney, M.D.
Medical Director

New Haven County Foundation
for Medical Care, Inc.
Woodbridge, CT

188th ANNUAL MEETING
# of the
CONNECTICUT STATE MEDICAL SOCIETY

Hartford Hilton Hotel
10 Ford Street, Hartford, Connecticut

April 30, May 1, 1980

COMMITTEE ON PROGRAM OF THE SCIENTIFIC ASSEMBLY

Dr. Fischbein

Fredric I. Fischbein, M.D., Middletown
James E. C. Walker, M.D., Farmington
Hugh F. Dwyer, New Haven
Leo P. Giardi, Hartford
Edward Dunn, Waterbury

A MESSAGE FROM THE PRESIDENT

I should like to extend an invitation to all members of the Connecticut State Medical Society to attend it's 188th annual meeting on Wednesday, April 30 and Thursday, May 1, 1980.

This two day session will be a highly informative and productive one and all concerned physicians should avail themselves of the opportunity to attend.

The House of Delegates meets on Wednesday, April 30 in an all-day session directed at transacting the business of the Society. Although this is primarily carried out by the House of Delegates any interested physicians may be heard at the pleasure of the House. Items and issues of vital concern to all of us will be discussed and actions will be taken that will have an important impact on the future of health care in our state. I ask for your involvement in these matters.

The annual dinner will be held on Wednesday evening, April 30 at 7:30 p.m. and I am certain our incoming President, W. Raymond James of Essex would appreciate a large turn out for his inauguration and inaugural address.

The scientific program on Thursday, May 1 presents us all with the opportunity to enhance our knowledge while obtaining CME credits with a minimum of effort and no additional tuition cost. I look forward to seeing you all at the meeting.

Edward A. Kamens, M.D.

GENERAL INFORMATION READ CAREFULLY

REGISTRATION

The registration desk will be located on the mezzanine floor and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket when and only if they register.

PARKING

There are ample parking facilities at the hotel and in the surrounding area.

TELEPHONE

Telephone messages will be received at Hartford 249-5611.

LUNCHEON

Luncheon will be served in the Terrace Room on the mezzanine floor on May 1st and ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.

HOTEL ACCOMMODATIONS

Persons who wish to remain overnight should make reservations not later than two weeks prior to opening date of the meeting. Reservations will be held until 6:00 P.M. on the day of arrival, unless later hour is specified. Please indicate in your letter that you are attending the Connecticut State Medical Society meeting. Your letter should be directed to the Front Office Manager, Hartford Hilton Hotel, 10 Ford Street, Hartford, Connecticut.

ANNUAL DINNER

The Annual Dinner will be held at the hotel on Wednesday, April 30, 1980. The social hour will be at 6:30 P.M. and the dinner at 7:30 P.M. All persons attending the dinner will be the guests of the Society at the social hour. Your reservations for dinner should be sent in as soon as possible to the CSMS office.

PROGRAM

The scientific portion of the Annual Meeting will be concentrated in one day, May 1, 1980. The general program will be held in the Capitol Ballroom between 10:30 and 4:00; and section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:00 P.M. in the rooms listed in the program.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL UNLESS OTHERWISE INDICATED

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING

ANNUAL MEETING OF THE HOUSE OF DELEGATES

WEDNESDAY, APRIL 30

CAPITOL BALLROOM MEZZANINE

Presiding:
JOSEPH S. SADOWSKI, M.D., *Hartford, Speaker of the House*

7:30 REGISTRATION OF DELEGATES—Mezzanine Floor
Continental Breakfast for Delegates and Official Guests

8:30 CALL TO ORDER
OPENING SESSION
REFERENCE COMMITTEE HEARINGS

1:15 LUNCHEON—Terrace Room Mezzanine

2:30 CALL TO ORDER—Capitol Ballroom
FINAL SESSION

6:15 ADJOURNMENT

ANNUAL DINNER OF THE SOCIETY

WEDNESDAY, APRIL 30

TERRACE ROOM MEZZANINE
Social Hour 6:30 P.M. Dinner 7:30 P.M.

PROGRAM

Presiding: EDWARD A. KAMENS, M.D., *Fairfield*

PRESENTATION OF GUESTS AND DELEGATES FROM STATE MEDICAL SOCIETIES

INAUGURATION OF INCOMING PRESIDENT
W. Raymond James, M.D., *Essex*

DINNER MUSIC

GENERAL SCIENTIFIC PROGRAM

THURSDAY, MAY 1

MORNING SESSION

8:15 REGISTRATION—Mezzanine

8:30- 10:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

10:00 INTERMISSION TO VISIT EXHIBITS—Mezzanine

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
W. Raymond James, M.D., Essex, President, Connecticut State Medical Society

Presiding: JAMES E. C. WALKER, M.D., *Farmington*

10:30 DEAD MEN TELL TALES — A PATHOLOGICAL RECONSTRUCTION OF AN AIRPLANE DISASTER
ROBERT R. McMEEKIN, M.D., J.D., Washington, D.C.; Lieutenant Colonel, Medical Corps, United States Army, Chief, Aerospace Division, Armed Forces Institute of Pathology; Associate Professor, Uniformed Services of University of Health Sciences.

11:10 IMPAIRED PHYSICIAN: RECOGNITION AND REHABILITATION
Moderator: Carl F. Hinz, Jr., M.D.,*Farmington*
LAWRENCE K. PICKETT, M.D., New Haven; Vice-President, Medical Affairs, Yale New Haven Hospital; Chief of Staff, Yale-New Haven Hospital; Associate Dean for Clinical Affairs, Yale University School of Medicine; President, Connecticut Medical Examining Board.

NORMAN ALISBERG, M.D., Bristol; Associate Clinical Professor of Medicine, University of Connecticut School of Medicine; Chief of Medicine, Bristol Hospital; Chairman, Committee on Medical Ethics and Deportment and Ad Hoc Committee on Physicians with Problems, Hartford County Medical Association.

11:50 WHY PHYSICIANS SHOULD WORRY ABOUT COSTS
JAMES S. TODD, M.D., Ridgewood, New Jersey; Chairman of the AMA's Ad Hoc Committee on Ethics; Attending Surgeon, Valley Hospital, Ridgewood; Instructor in Surgery, Columbia College of Physicians and Surgeons, New York.

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON—Terrace Room

AFTERNOON SESSION

Presiding: EDWARD DUNN, M.D., *Waterbury*

SYMPOSIUM—RUN FOR YOUR LIFE?

2:00 CAN WE IDENTIFY INDIVIDUALS AT RISK FOR EXERTIONALLY INDUCED SUDDEN DEATH?
THOMAS B. GRABOYS, M.D., Boston; Assistant Professor of Medicine, Harvard Medical School; Attending Cardiologist, Peter Bent Brigham Hospital; Director of Clinical Services, Lown Cardiovascular Laboratories, Harvard School of Public Health.

2:30 PHYSIOLOGY OF EXERCISE
NORMAN BRACHFELD, M.D., New York; Associate Professor of Medicine, Cornell University Medical College; Associate Attending Physician, New York Hospital.

3:00 PREVENTION AND TREATMENT OF LOWER EXTREMITY INJURIES IN JOGGERS
PETER JOKL, M.D., New Haven; Associate Professor of Surgery (Orthopedics) Yale University School of Medicine; Chief of Athletic Medicine, Yale University Health Services.

3:30 INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

THURSDAY, MAY 1
MEETINGS OF SECTIONS OF THE SOCIETY

MORNING SECTION PROGRAMS

SECTION OF FAMILY PRACTICE

8:30 A.M. Room 424

President: John E. Donnelly, M.D., *Shelton*
Secretary: Carl C. Conrad, M.D., Colchester

MANAGEMENT OF DEPRESSION IN FAMILY PRACTICE
Jonathan Himmelhoch, M.D., Pittsburgh, Pennsylvania; Chief, Affective Disorders Clinic, Western Psychiatric Insti-

tute and Clinic (Program supported by grant from Merck, Sharp and Dohme)

SECTION OF FORENSIC MEDICINE

8:30 A.M. New York-Washington Rooms

President: Bertrand P. Bisson, M.D., Waterbury
Secretary: G.S. Gudernatch, M.D., Sharon

Business Meeting (Breakfast will be served)

INFORMAL DISCUSSION: Guest: Robert R. McMeekin, M.D., J.D., Washington, D.C.; Lieutenant Colonel, Medical Corps, United States Army, Chief, Aerospace Division, Armed Forces Institute of Pathology; Associate Professor, Uniformed Services of Health Sciences.

SECTION ON INTERNAL MEDICINE

8:30 A.M. Boston-Buffalo Rooms

President: Arnold M. Koff, M.D., Avon
Secretary: Leonard E. Grauer, M.D., New Haven

NEWER CONCEPTS IN THYROID FUNCTION TESTING

Bruce F. Bower, M.D., Hartford, Connecticut; Head, Endocrinology, Hartford Hospital.

NEWER CONCEPTS IN DIFFERENTIAL DIAGNOSIS OF THYROID NODULES

George E. Reardon, M.D., Hartford, Connecticut: Head, Endocrinology, St. Francis Hospital and Medical Center.

SECTION ON OTOLARYNGOLOGY

10:00 A.M. Yankee Silversmith, Wallingford

President: Timothy L. Curran, M.D., Hartford
Secretary: John W. Cavo, Jr., M.D., New Britain

PEDIATRIC AIRWAY PROBLEMS

Gerald B. Healy, M.D., Boston, Massachusetts; The Children's Hospital Medical Center.

WHAT'S NEW IN WASHINGTON?

Harry W. McCurdy, M.D., Bethesda, Maryland; Executive Director, American Council of Otolaryngology.

SURGICAL TECHNIQUES IN CHRONIC EAR DISEASE

John Shea, M.D., Memphis, Tennessee; Professor of Otolaryngology, University of Tennessee School of Medicine.

SECTION ON PHYSICAL MEDICINE AND REHABILITATION

8:30 A.M. Rooms 436-440

President: Philip B. Arnold, M.D., Danbury
Secretary: Josephine M. Fuhrmann, M.D., New Haven

MYOFASCIAL PAIN SYNDROMES: DIAGNOSIS AND MANAGEMENT

Janet Travell, M.D., Washington, D.C., Professor of Medicine, George Washington University School of Medicine.

SECTION ON PSYCHIATRY

8:30 A.M. Room 408

President: Cyril Waynik, M.D., Fairfield
Secretary: Richard M. Bridburg, M.D., Hartford

UPDATE—PSYCHIATRY OF AFFECTIVE DISORDERS

Charles Shamoinan, M.D., New York; Clinical Associate Professor of Psychiatry, Cornell Medical School.

SECTION ON PULMONARY DISEASES

8:30 A.M. Rooms 412-416-420

President: Norman L. Dean, M.D., Derby
Secretary: Frederick L. Sachs, M.D., New Haven

SYMPOSIUM ON CURRENT CONCEPTS IN MECHANICAL VENTILATION AND ITS HEMO-DYNAMIC EFFECTS

David R. Dantzker, M.D., Ann Arbor, Michigan; Associate Professor of Medicine, University of Michigan Medical School.

Warren R. Summer, M.D., Baltimore, Maryland; Associate Professor of Medicine, John Hopkins University School of Medicine.

Philip G. Boysen, M.D., Gainesville, Florida; Associate Professor of Medicine, University of Florida College of Medicine.

AFTERNOON SECTION PROGRAMS

SECTION ON ALLERGY

6:00 P.M. Hotel Sonesta, Hartford

President: Louis M. Mendelson, M.D., Hartford
Secretary: Jay E. Selcow, M.D., Hartford

CLASSIFICATION OF MOLDS, CULTURE, TECHNIQUE AND OBSERVATIONS

Ira Salkin, M.D., Albany, New York; Division of Laboratories and Research, New York State Department of Health.

Dinner To Follow

SECTION ON ANESTHESIA

4:30 P.M. Hotel Sonesta, Hartford

President: David L. Maxham, M.D., Fairfield
Secretary: Raymond E. Bradley, Jr., M.D., Woodbridge

VASODILATORS IN ANESTHESIA

Herman Turndoff, M.D., New York City; Professor and Chairman, Department of Anesthesia, New York University School of Medicine.

SECTION ON GASTROENTEROLOGY

4:00 P.M. Sheraton Hartford Hotel, Hartford

President: Morton Bender, M.D., New Haven
Secretary: David I. Grayer, M.D., Bridgeport

SURGERY FROM THE PATIENTS POINT OF VIEW IN CHRONIC INFLAMMATORY BOWEL DISEASE

Samuel Meyers, M.D., New York City; Assistant Professor, Mt. Sinai School of Medicine.

Reception to Follow

SECTION ON OBSTETRICS AND GYNECOLOGY

4:00 P.M. Rooms 436-440

President: Richard F. Jones, III, M.D., Hartford
Secretary: John M. Gibbons, Jr., M.D., Hartford

LASER THERAPY

SECTION ON OPHTHALMOLOGY

3:00 P.M. New York-Washington Rooms

President: John B. Franklin, M.D., Hartford
Secretary: John W. Redmond, M.D., Meriden

3:00 MANAGEMENT OF FREQUENTLY ENCOUNTERED PROBLEMS IN THE POSTERIOR SEGMENT
Arnold J. Kroll, M.D., Boston, Massachusetts; Associate Professor of Clinical Ophthalmology, Tufts University School of Medicine.

4:00 Business Meeting

5:30 Reception and Dinner—Hartford Room

7:30 Guest Speaker: Robin Cook, M.D., Boston, Massachusetts; Author of "Coma"
Subject: "M.D. VS. HOLLYWOOD"
Spouses are invited.

SECTION ON ORTHOPEDICS

3:30 P.M. Hunt Memorial Bldg.
230 Scarborough St., Hartford

President: Robert B. Sirkin, M.D., New Britain
Secretary: John D. Haugh, M.D., Hartford

INDICATIONS AND RESULTS OF TOTAL ARTHROPLASTIES AND ANKLE FUSIONS
Theodore Waugh, M.D., New York City, Professor and Chairman, Department of Orthopedic Surgery, New York University School of Medicine.

SECTION ON PATHOLOGY

4:00 P.M. Room 424

President: Martin S. Nadel, M.D., Middletown
Secretary: James A. E. Spencer, Greenwich

CORRELATION OF LIGHT AND E.M.—GYNECOLOGICAL SURGICAL PATHOLOGY
Bernard Gondos, M.D., Farmington, Connecticut; Professor of Pathology, University of Connecticut School of Medicine; Director, Anatomic Pathology, University of Connecticut Health Center.

SECTION ON PROCTOLOGY

4:00 P.M. Room 404

President: Bernard J. Kaplan, M.D., Hartford
Secretary: Sanford Savin, M.D., Bridgeport

Business Meeting

SECTION ON RADIOLOGY

4:00 P.M. Buffalo Room

President: Jack P. Lawson, M.D., New Haven
Secretary: Edward F. Fox, M.D., Bristol

Business Meeting

Election of Officers

SECTION ON SURGERY

4:00 P.M. Capitol Ballroom

President: Malcolm M. Ellison, M.D., New London
Secretary: John Shoukimas, M.D., Hartford

4:00 TRAUMA CARE REGIONALIZATION: ENLIGHTENMENT OF INFRINGEMENT
William H. Frazier, M.D., New Haven, Connecticut; Associate Professor of Surgery (Plastic), Yale University School of Medicine; Medical Director of Emergency Services, Yale-New Haven Hospital; Director, Burn Service and Yale Trauma Program, Yale-New Haven Hospital.

4:30 Business Meeting

5:15 JOINT SOCIAL HOUR AND DINNER WITH CONNECTICUT SOCIETY OF AMERICAN BOARD SURGEONS
Guest Speaker: Mr. Jack Shepherd, Norwich, Vermont: Running enthusiast, Journalist and Author.
Subject: "BACK OF THE PACK"

SECTION ON UROLOGY

4:00 P.M. Room 420

President: Richard P. Lena, M.D., New Haven
Secretary: Haik Kavookjian, M.D., Stamford

Business Meeting

Scientific Program

AUXILIARY TO THE CONNECTICUT STATE MEDICAL SOCIETY

THIRTY-SIXTH ANNUAL MEETING

THURSDAY, MAY 1

AVON OLD FARMS INN, AVON

President: Mrs. Joseph Czarsty, Oakville
Recording Secretary: Mrs. Wayne B. Andrus, Portland
Corresponding Secretary: Mrs Earle A. Herbert, Willimantic

10:00 Business Meeting

12:00 Reception

12:30 Luncheon

2:30 Art Demonstration, Farmington Valley Art Center, Avon.

IMPORTANT—PLEASE NOTE

Due to conflict with national meetings, the following Sections of the Society will not be meeting on May 1. The programs, dates and time follow:

SECTION ON DERMATOLOGY

11:00 A.M. May 7, 1980

Jake's Restaurant (formerly Mermaid Tavern)
6905 Main Street, Stratford

President: Melvin P. Coolidge, M.D., Fairfield
Secretary: Ivan Cohen, M.D., Fairfield

THE MECHANICS OF STATE MEDICINE

Mr. Steven Press, Hartford, Connecticut; Chief Administrative Officer for the Connecticut State Department of Income Maintenance.

SECTION ON NEUROSURGERY

4:30 P.M. May 9, 1980

Bee & Thistle Inn, Old Lyme

President: Donald W. Cooper, M.D., New London
Secretary: John N. German, M.D., New London

PROGRAM TO BE ANNOUNCED

SECTION ON PEDIATRICS

5:00 P.M. Shore & Country Club
Gregg Point, East Norwalk

President: E. Maurice Wakeman, M.D., Guilford
Secretary: Katherine Prioli, M.D., New London

5:00 Business Meeting
6:00 Social Hour
6:45 Dinner - Guest Speaker

SPECIAL NOTICES

CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

The Yale University School of Medicine has accredited the scientific program of the Society's Annual Meeting for Category One Credit toward the AMA Physician's Recognition Award. Credit is granted in this category on an hour-for-hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for 4 hours of prescribed credit for the general lectures and the family practice section meeting, and one hour of elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

SPECIAL NOTICES

THE CONNECTICUT STATE MEDICAL SOCIETY
acknowledges with thanks educational program grants received from:

Ciba-Geigy Pharmaceuticals, Summit, New Jersey
Eli Lilly and Company, Indianapolis, Indiana
Parke, Davis & Company, Detroit, Michigan
The Purdue Frederick Company, Norwalk, Connecticut
A. H. Robins Company, Inc., Richmond, Virginia
Smith Kline and French Laboratories, Philadelphia, Pennsylvania

Our exhibits contribute to the value of our Scientific Assembly by presenting goods and services of interest and importance to physicians and their families. Personal visits at the booths will increase your understanding of the materials and programs on display.

TECHNICAL EXHIBITS

Aetna Life and Casualty, Hartford, Connecticut
American Electromedics Corporation, Acton, Massachusetts
Ayr Insurance Agency, New Haven, Connecticut
Boehringer Ingelheim Ltd., Ridgefield, Connecticut
J. C. Carter and Company, Darien, Connecticut
Datamedic Corporation, Plainview, New York
Encyclopedia Britannica, Chicago, Illinois
Group Insurers, Hamden, Connecticut
Hoechst-Roussel Pharmaceutical, Inc., Somerville, New Jersey
Kabi Group, Inc., Greenwich, Connecticut
Med-X Health Service, Inc., West Hartford, Connecticut
Merck Sharp & Dohme, West Point, Pennsylvania
Pfizer Laboratories, Clifton, New Jersey
Sandoz Pharmaceuticals, East Hanover, New Jersey
Upjohn Company, Kalamazoo, Michigan
United States Army Medical Department
United States Naval Recruiting Service

in Brief

A summary of AMA, medical & health news

Executive Exchange Program, an informal consulting service, will be offered to members of the American Assn. of Medical Society Executives. The aim of the program is to provide executives with information, new ideas, and solutions based on the success of other AAMSE executives in many subject areas. A reference file of members with special expertise will be maintained at AAMSE Headquarters in Chicago. Communication by members with the expert can take place by telephone, mail or on-site visit. For further information contact AAMSE Headquarters, 535 N. Dearborn St., Chicago, 60610 (312) 751-6733.

Qualifications of jail health facilities will be reviewed by the newly formed AMA Consultant Advisory Group on Accreditation. The five-member group will weigh assessment by AMA Jail Health Project staff against AMA standards for jail health care, which have been used to accredit health facilities in 56 jails nationwide. Development of the standards was funded by Law Enforcement Assistance Administration grants.

Physicians can receive a $50 discount, or a free copy of *AMA Drug Evaluations,* if they register before March 15 for any of the three upcoming AMA seminars on the overall purpose and responsibilities of a medical staff. A special segment on medical malpractice will be included. The seminars, "Medical Staff: Friend or Foe," will be held April 24-25 in Chicago, May 9-10 in Portland, Ore., and Nov. 6-8 in New Orleans. Registration fee before discount is $250 for AMA members, $350 for nonmembers. For more information contact the Dept. of Hospitals and Health Facilities, AMA Headquarters.

"While physicians should be conscious of costs and should not provide or prescribe unnecessary services or unnecessary ancillary facilities, concern for the patient and the quality of care the patient receives comes first," the AMA Judicial Council states in the newly published 1979 edition of *Judicial Council Opinions and Reports*. The booklet also contains new ethical standards on in vitro fertilization, euthanasia, and patient confidentiality. The AMA has formulated and reviewed ethical guidelines since its founding in 1847. Cost is $2 each for 1-10 copies; $1.80 each for 11-49; $1.60 each for 50 or more; and $2.50 each for foreign orders. To order write OP-437, AMA Order Dept., P.O. Box 821, Monroe, Wis. 53566.

The total AMA membership figure for 1979 was 223,000, an increase of 12,700 over the 1978 figure. In 1979 the AMA had 192,100 dues-paying members and 30,900 dues-exempt members. Of the dues-paying total, 151,600 were regular members, 20,300 were interns and residents, and 20,200 were students. All membership goals were exceeded last year, with regular members numbering 3,900 more than in 1978 and resident and student membership increasing 8,800 over 1978.

The number of complaints against physicians under investigation increased by nearly 85% in 1978 over the total a year earlier, a 1978 AMA survey shows. The increase in investigations—from 3,662 in 1977 to 6,801 in 1978—can be attributed in part to the growing legal immunity offered to those who report offenses. The increase in actual disciplinary actions against physicians—from 685 in 1977 to 1,476 in 1978—continues an upward trend first noted by the AMA in 1971, and can be partially attributed to the addition of more and varied forms of discipline.

AMA concern for impaired physicians has led to three conferences, model legislation for treatment and rehabilitation, and a quarterly newsletter on programs available. A symposium on the impaired physician was included as part of the recent AMA Winter Scientific Meeting in San Antonio. For information on impaired physician programs, write Dept. of Mental Health, AMA Headquarters.

The first in a series of AMA "Theme" Meetings, "Coronary Artery Disease: A Comprehensive Review," will be held April 9-12 in Los Angeles. The conference is worth 32 hours of Category 1 continuing medical education credit in cardiology, with 21 other postgraduate courses worth 6 hours of CME credit each being offered simultaneously. Cosponsor of the conference is the American College of Cardiology. Participating societies are the American Assn. for Thoracic Surgery, American Society of Clinical Pathologists, and the American Society of Clinical Pharmacology and Therapeutics. The program is designed for the physician responsible for the primary diagnosis and management of coronary artery disease. For registration information contact the Dept. of Meeting Management, AMA Headquarters.

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Francis G. Sweeney
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

COUNCIL MEETING

Wednesday, February 13, 1980

Attendance

Present were: Drs. Kamens, James, Canzonetti, Backhus, Mendillo, Sadowski, Freedman, Hess, Van Syckle, Fabro, Whalen, Cramer, Friedberg, McGarry, Rubinow, Anderson, Magram, Parrella, Zlotsky, Jameson, Beck, Abbot, Seide, Barrett, Shenker, Eslami, Tierney, Bobruff and Sonnen.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Sweeney, Mr. Brunnell, Mr. Fiorentino and Mr. Tomat (FCMA).

Approval of Minutes

It was VOTED to approve the minutes of the meeting of December 13, 1979, as published and distributed with the following amendment made by Dr. Guy Van Syckle. Substitute the following report on the AMA Convention to replace the report published on page 3 of the December 13 minutes:

AMA Convention

Dr. Guy Van Syckle reported on the activities at the recently concluded AMA Convention.

The AMA House of Delegates reaffirmed its policy on National Health Insurance, its support for continuation of the PSRO program, and its confidence in the support of the Voluntary Effort. The House received a seventy-four page background report from the Council on Medical Education entitled, "Future Directions for Medical Education" which proposed sweeping changes in medical education. The Delegates filed this report and directed that its suggestions become an agenda of issues for discussion followed by the development and review of more specific recommendations. He reported that the membership issue is an ongoing concern to the House. Although there has been a modest increase in the total dues paying members, the percentage of AMA's members compared to the total United States physician population continues to decline. There has been encouraging increase in the number of medical students and resident physicians which now total over 20,000 members in each category. He recommended that the Council give serious consideration to the proposition of facilitating medical student and resident physician membership in both the State Medical Society and AMA.

Resolution on Elderly Health Screening Adopted by House of Delegates, 11/15/79—Dr. Edward Kamens reported on his meeting with representatives of the Elderly Health Screening Council and other matters pertaining to this program, including the report of the Committee on Public Health. After considerable discussion of the in-depth report of the Committee on Public Health, it was agreed by the Council that the concerns of the House of Delegates about the Program were legitimate but that the investigative study by the committee revealed sufficient information for the Council of the CSMS to recognize that the intention on the part of the Elderly Health Screening Program was good and also that the Society desires to have a more cooperative relationship in the future with the Program. It was then VOTED to recommend to the House of Delegates at its coming meeting on April 30 that it reconsider its previous action taken on November 15, 1979. In order to obtain additional information to present to the House of Delegates, the following resolution was adopted:

WHEREAS: Multiphasic screening has much to recommend it; and

WHEREAS: The Council of the CSMS is concerned about how the information obtained is dispensed; and

WHEREAS: The professional liability of the practitioner to whom such patients and data are referred has not been resolved; and

WHEREAS: Many of these patients incorrectly perceive this screening process to constitute a complete physical examination; and

WHEREAS: Further clarification about the Program is needed; therefore be it

RESOLVED: That an ad hoc committee be formed consisting of representatives from the CSMS Committee on Public Health, Connecticut Society of Internal Medicine, Connecticut Society of Family

Practitioners and Connecticut Society of OB-GYN charged with the responsibility of examining these problems for a report back to the Council at least one month in advance of the next meeting of the House of Delegates, which is April 30, 1980.

Report from the Committee on Professional Liability

Dr. Gioacchino Parrella reviewed for the Council the efforts of the Committee on Professional Liability in hearing the presentations of consultants submitting proposals for a feasibility study looking toward the possible formation of a captive insurance company for CSMS.

After discussion, the Council VOTED to approve of the Committee recommendation to pursue the feasibility study and to engage the services of American Health Systems, and that firm's recommended actuary, to perform the task.

It was also VOTED that the Committee on Professional Liability be empowered to spend up to $50,000, if necessary, for this study with the understanding that the entire process will be carefully reviewed and undertaken in stages.

Committee on Professional Liability

After discussion of the committee report, it was VOTED to grant permission to the Committee on Professional Liability to continue its efforts in studying the feasibility of mandatory screening panels and their mode of operation.

Ad Hoc Committee on Medicare-Medicaid

After discussion concerning the Medicare-Medicaid Physician Fee Reimbursement Equity the Council VOTED to direct a letter to Governor Grasso seeking the following statistics:

A. Data Base for fiscal years 7/1/77 to 6/30/78; and 7/1/78 to 6/30/79.

B. The total number of beneficiaries and their dependents.

C. The total cost of the Title XIX Program each year with a breakdown for M.D. provider expense in hospital emergency room care, out-patient clinics and office visits (and further breaking down the office visits into medical, pediatrics, OB, GYN).

D. In-hospital care should be broken down into medical and surgical procedures with a breakdown of the type of surgical procedures and the number of each procedure and cost (i.e., cholecystectomy, hernia repair, deliveries, hysterectomy, fracture treatment, etc.).

Following a study of these statistics CSMS will request an audience with the Governor to discuss the findings.

Intern/Resident and Student Membership in CSMS

Following discussion it was VOTED to approve of the concept of medical student and intern/resident representation in the CSMS House of Delegates and to instruct the Subcommittee to Revise the Bylaws to report back to the Council at its April 3 meeting with an appropriate mechanism to achieve this goal.

Report - Subcommittee on Preliminary Study of Nominations

With several amendments, it was VOTED to approve the report of the Subcommittee and to transmit a complete slate of nominees to the House of Delegates for election, with Council recommendation for approval.

House of Delegates Action - Public Information Program

Mr. Norbeck reported to the Council on his meetings with several public relations/consultant firms and Connecticut Public Television.

After discussion, it was tentatively agreed to enter into a relationship with Creamer, Inc. of Hartford, Connecticut; however, prior to a definite commitment, it was VOTED to request representatives of the subject firm to make a presentation to the Council on their proposed program, including a financial projection. It was also VOTED to invite members of the current Committee on Public Relations and proposed new members of the committee to attend the meeting set for Wednesday, March 12, 1980 (3 P.M. - 5:00 P.M.).

James H. Root, M.D.

It was VOTED to make Dr. James H. Root a dues exempt member of the CSMS until such a time as he is eligible for life membership.

American Association of Medical Assistants (AAMA) Connecticut Chapter

It was VOTED to appoint Drs. Gene Adams, New London, Jay A. Graves, Old Lyme, and Patrick Carolan, Bridgeport, as advisors to the AAMA.

Life Members

It was VOTED to accept for information the following list of Life Members:

John C. Allen, West Simsbury (H) - 1/1/80
Fred A. Anderson, Norwich (NL) - 1/1/80
Ruth M. Anderson, Norwich (NL) - 1/1/80
Roy N. Barnett, Westport (F) - 1/1/80
Alfred E. Brewer, Salisbury (L) - 1/1/80
Philip S. Brezina, Bristol (H) - 1/1/80
John Carangelo, Hartford (H) - 1/1/80
Rocco Cassone, Stamford (F) - 1/1/80
Mario G. Conte, New Haven (NH) - 1/1/80
William H. Curley, Bridgeport (F) - 1/1/80
A.S. Deming, Hartford (H) - 1/1/80
Edward G. Deming, Hartford (H) - 1/1/80
John Donnelly, Hartford (H) - 1/1/80
Henry J. Gloetzner, Norwalk (F) - 1/1/80
Gerald S. Greene, Hartford (H) - 1/1/80
Clarence W. Harwood, Middletown (M) - 1/1/80
Francis W. Helfrick, Manchester (H) - 1/1/80
Harry H. Hershman, Bristol (H) - 1/1/80

Lloyd N. Hockmuth, West Simsbury (H) - 1/1/80
Paul E. Kaunitz, Westport (F) - 1/1/80
Frank E. Lach, New Haven (NH) - 1/1/80
Vincent A. Lynch, Bridgeport (F) - 1/1/80
Edward Martin, New Britain (H) - 1/1/80
Ward J. McFarland, New London (NL) - 1/1/80
John J. Milici, West Haven (NH) - 1/1/80
Salvatore S. Piacente, Hartford (H) - 1/1/80
John S. Poczabut, Stamford (F) - 1/1/80
William D. Riordan, West Hartford (NH) - 1/1/80
John D. Ryan, Stamford (F) - 1/1/80
Elias Savitsky, Stamford (F) - 1/1/80
Walter A. Schloss, West Hartford (H) - 1/1/80
Charles Sheard, Stamford (F) - 1/1/80
Harold P. Stetson, Southington (H) - 1/1/80
Bernard D. Svedlow, Stamford (F) - 1/1/80
Norris P. Swett, Hartford (H) - 1/1/80
Charles A. Tucker, Hartford (H) - 1/1/80
Eugene H. Walzer, Bridgeport (F) - 1/1/80
Joseph M. Wool, New London (NL) - 1/1/80

Miscellaneous

Dr. Van Syckle read a letter received from Dr. Hilliard Spitz pertaining to the activity of the Ad Hoc Committee for the Connecticut Ambulatory Care Study. It was VOTED that no dissemination of information concerning the study should be made until the report had been accepted by HEW and that the Ad Hoc Committee should *wait* for a reply from HEW.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on February 13, 1980. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

In Memoriam

AYRES, PAYSON B., University of Toronto, Canada 1932. He was a obstetrician-gynecologist in the Fairfield area since 1934. During World War II he served in the U.S. Navy Medical Corps with the rank of lieutenant colonel attached to Marine Intelligence. From 1942-1946 he served with the Pentagon, teaching basic Japanese at Princeton University and being in action in the Pacific Theater's Guadalcanal combat zone, to and through the initial occupation. He was president of both the Greenwich and the Fairfield County Medical Societies and served, from 1964 to 1968, as an associate councilor to the Connecticut State Medical Society. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Ayres died January 9, 1980, at the age of 74.

BARRY, JOSEPH C., Boston University Medical School, 1933. Dr. Barry was a general practitioner in the Hartford area since 1935 and was the physician for the Manchester school system for 24 years. He was also a past president of the Manchester Memorial Hospital staff and was a member of the hospital's staff for 34 years. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Barry died January 28, 1980, at the age of 77.

BIRD, FREDERICK S., University of Vermont, 1933. Dr. Bird was a general practitioner in the Hartford area since 1935, and was a former chief of medical and pediatric service at Bristol Hospital. He served as a Major in the Army Medical Corps in New Guinea and the Philippines from 1942 to 1946. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Bird died January 21, 1980, at the age of 71.

CAMPBELL, SHERBURNE, University of Vermont, 1923. Dr. Campbell was a ophthalmologist in the New Haven area since 1927. He was a veteran of World War I and World War II and retired from the United States Navy after achieving the rank of commander. Dr. Campbell retired from the medical staff of Meriden-Wallingford Hospital in 1973 but remained with the hospital as an emeritus member. He served as the hospital's chief of ophthalmology several times during his career. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Campbell died February 12, 1980, at the age of 80.

CHIROT, MICHEL, University of Paris, 1939. Dr. Chirot was a anesthesiologist in the Tolland area since 1973. He served in the French Army from 1939 to 1946 and was affiliated with the Johnson Memorial Hospital. He was a member of the Tolland County Medical Association and the Connecticut State Medical Society. Dr. Chirot died January 16, 1980, at the age of 66.

HACKBARTH, CLIFFORD J., University of Louvain, Belgium, 1964. Dr. Hackbarth was a general practitioner in the New London area since 1965. Dr. Hackbarth was a former director of health in Old Lyme and a former school physician and medical examiner, also in Old Lyme. He was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Hackbarth died January 10, 1980, at the age of 45.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Physician's office suite on Burnside Ave., East Hartford, available at moderate rental. Contact Ms. Green, 233-3780.

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Hematology/Oncology: July '80. Age 39. AB-elig. MD: India. Int. and res.: Jamaica Hosp., NY. Fellowship's: VA Hosp., NY, Nassau Hosp., NY and Emory. Solo, grp. or institutional practice desired in CT. P.S. Balasubramaniam, M.D., 826-6 Clifton Ct. Ctr., NE, Atlanta, GA 30329.

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OPHTHALMOLOGY

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The Planning and Preparation for Breast Cancer Reconstruction—A Perspective Approach for General Surgeons

MARVIN S. ARONS, M.D., D.M.D.

"All is flux, nothing stays the same".
Heraclitis (540-480 B.C.)

I. Breast Cancer Perspectives

Breast cancer is the most common female neoplasm and the leading cause of cancer death in women. Seven percent of women will develop breast cancer during their lives and 6%-10% of all women who live to age 85 will develop this carcinoma. One out of 15 all newborn girls will develop breast cancer in their lifetime. Every 15 minutes one woman will die of this disease. In the United States about 100,000 new cases of breast carcinoma are detected each year; over 30,000 women die of malignancy; and about 90,000 American women undergo some type of mastectomy each year.[1,2,3]

At present, surgeons and patients alike would probably agree that cure is more important than contour. Fifty-two percent of women are in a stage of in situ or localized cancer when first diagnosed. The absolute five year survival rate for lobular, infiltrating carcinoma is reported at 70%. Prognosis for all types of breast cancer changes significantly only after more than three lymph nodes are involved (absolute five year survival for 1-3 positive axillary nodes—63%-59%).[4]

II. Psychologic Perspectives

It has been estimated that approximately 80% of the 90,000 women with some type of radical mastectomy finally adjust to the stress of their situation and appear to lead a "normal" life. The other 20% remain emotionally disturbed and should be assisted in seeking plastic surgical and/or psychological consultation.[2] The great majority of women fear not only death from cancer but also mutilation of their bodies. Depression is a frequent complication.[3,5] The degree of injury to self esteem consequent to mastectomy is a function of the total personality.[6]

Currently, all too many mastectomy patients arrive in the office of a plastic surgeon after having read a newspaper article or magazine feature or after watching a TV show or demonstration. Yet, with the changes in surgical procedures for breast and with the replacement of dogmatic and accustomed techniques with scientific inquiry and statistics, more patients than ever are being referred by their general surgeons who have performed the mastectomy.

III. Mastectomy Perspectives

In 1977, 63% of American women undergoing surgical therapy of their breast cancer had a modified radical operation while only 22% had a classical radical procedure.[4] It was the consensus of a panel of cancer specialists convened by the National Cancer Institute on June 5, 1979 that for the majority of women with Stage I and Stage II primary breast cancer, total mastectomy leaving the pectoral muscles intact with axillary node dissection was the preferred surgical treatment.[7]

Also known as the "modified radical mastectomy" the newly endorsed procedure promises a less disfiguring treatment for the approximately 25,000 women in this category who might otherwise undergo radical mastectomies each year.

In addition, the panel endorsed a two-step procedure to separate the diagnostic biopsy from the definitive therapeutic effort in breast cancer treatment. No longer will optimum practice include examination of the frozen section while the patient is on the operating table and performance of any additional surgery forthwith without further patient (and perhaps other) consultation.

"It is the consensus of this panel that a procedure which preserves the pectoral muscles, a total mastec-

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MARVIN S. ARONS, M.D., D.M.D., Chief, Section of Plastic Surgery, Hospital of St. Raphael; Associate Clinical Professor, Plastic Surgery, Yale University School of Medicine.

tomy with axillary dissection, provides equivalent benefit to women who have Stage I and selected Stage II breast cancer and can be designated as the current standard treatment. In addition it is the consensus of the panel that the two-step procedure is a reasonable step and should be the procedure of choice in the majority of cases."[8]

Thus, the death knell for a century old tradition in the treatment of early localized breast cancer has been sounded. For such cases the Halstead mastectomy appears moribund. Also, with the advent of the two-stage delayed procedure, the general surgeon not only can contemplate and decide his next technical maneuver but can obtain advice from and inform his patient about available reconstructive procedures.

With Board-certified plastic surgeons now in Bridgeport, Danbury, Greenwich, Hartford, Meriden, Middletown, New Haven, New London, Norwalk, Stamford and Waterbury, no Connecticut general surgeon is far from consultation for that group of selective and selected patients interested in or desirous of post mastectomy reconstructive surgery.

IV. Technical Perspectives

A. Incision

The modified radical mastectomy incision sparing the pectoral muscles should be planned to first adequately encompass the cancer and then fulfill the cosmetic requirements of the patient. Nothing is more difficult to hide with modern revealing styles than an incision ascending to the acromio-clavicular area. Such an incision for the new preservation-type mastectomy must be aesthetically decried (Figure 1). A linear-oblique transverse type ellipse should instead be planned with the superior lateral end in the axillary area.[9] Though some general surgeons claim it hinders exposure and vision, the majority of experienced surgeons find no difficulty in adaptation (Figure 2).

The incision worn by the patient is the badge of mastectomy inflicted on her by her surgeon.[3] Therefore, the wound closure should be meticulously performed utilizing nonabsorbable subcuticular sutures and coapting and leveling sutures for the skin edges. Unsightly "dog ears" need not remain in the axilla nor near the sternum if the elliptical resection is planned with care and plotted with a marking pen.

A fast skin to skin closure may impress the operating room staff but it may leave the patient with deforming, unsightly scars whether or not she ever undergoes breast reconstruction. All surgery should be "reconstructive". Remember, 73% of post mastectomy complications are wound related.[10]

Through the mid to lateral portion of the scar about six months post mastectomy will be inserted subcu-

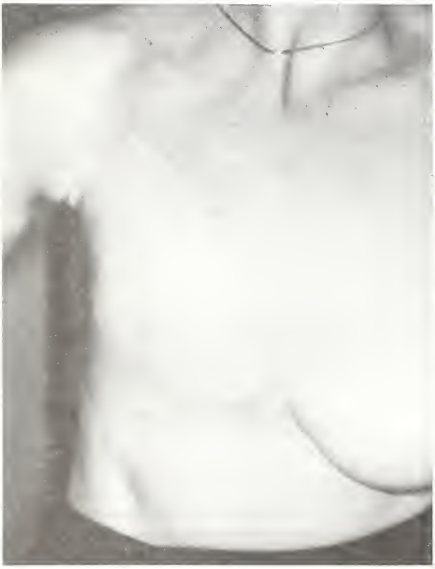

Figure 1
Technically inappropriate vertical scar following modified right radical mastectomy sparing pectoral muscles; scar is wide, depressed, and with prominent marks and permanent inferior "dog-ear".

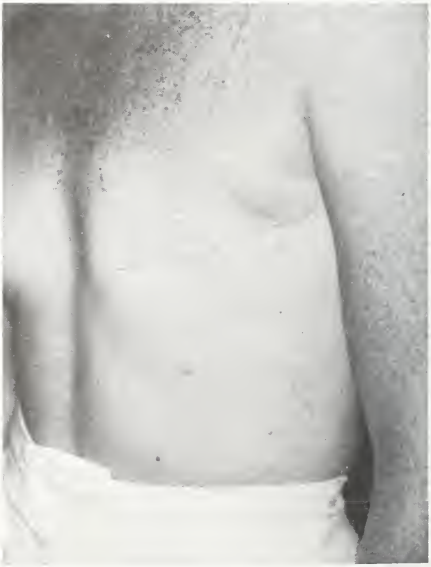

Figure 2
Most acceptable transverse oblique scar following left modified radical mastectomy. This type of scar affords the patient the opportunity of reconstruction without need of pedicle flap.

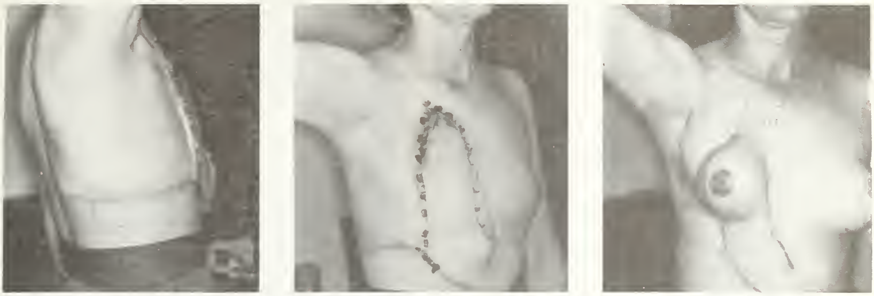

Figure 3
Transverse medially-based abdominal pedicle flap to reconstruct chest wall after radical mastectomy with skin graft. *Left*—right lateral donor site; *Middle*—flap transposed; *Right*—right breast reconstructed.

taneously or subpectorally one of a variety of types of silicone prostheses.[3 11 12] About 85% of patients will not require the insertion of additional full thickness tissue in the form of a latissimus dorsi pedicle flap[13] or a transverse abdominal medially based pedicle flap[14] (Figure 3). What is necessary is wide undermining and the use of two suction catheters.[14 15]

Although a silicone gel prosthesis may be forced into a thin-walled, tightly stretched pocket on the chest wall, the aesthetic result is poor and the likelihood of ulceration and extrusion is great. When skin flaps are especially thin and tight, scarring is marked, skin grafts are present or there is radiation damage, it must be realized that additional healthy skin flaps will be required. Unfortunately, this usually requires multiple stages and there must be greater motivation on the part of the patient.[14]

B. Timing

Unless the likelihood of local recurrence is great, most authors recommend waiting about six months so that the wound can heal, the vascularity of the flaps can be assured, and the skin becomes pliable.

If the surgeon is concerned that his patient is at an increased risk for local recurrence, he may wish to postpone reconstruction for a period of two years since 70%-90% of recurrences will occur during that time. However, it has been shown that a local recurrence usually heralds distant spread of the disease and the five-year survival of patients with local recurrence has been reported to be less than 5%. Even with treatment, the mean survival internal after chest wall recurrence is less than three years. Therefore, delaying reconstruction for the fear of masking local recurrence may not be sound.[15]

C. Nipple-Areolar Complex

The multiplicity of methods of reconstructing the nipple and areola testifies to the lack of one single perfect acceptable technique.[12 13 16-20] It is neither the purpose of this paper to discuss this problem nor even to list all the many references, but it is necessary to enumerate the following facts:

1. The nipple-areola complex can be "harvested" as a free composite graft to be "banked" in the inguinal region above (Figure 4) or below the groin crease.

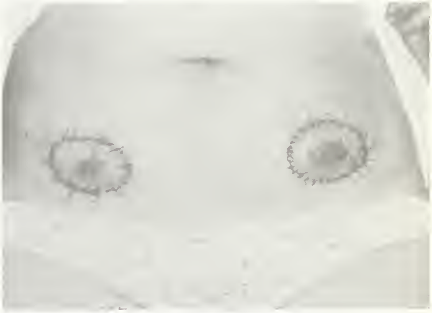

Figure 4
Bilateral composite nipple-areolar grafts positioned in inferior abdominal crease area.

2. This procedure is performed prior to mastectomy and while a biopsy from the nipple-ductal system is sent for frozen section.
3. If the nipple and areola are not spared, all is not lost—providing the other breast is present with its nipple-areola unit as a future sharing donor site.
4. Should there be a bilateral mastectomy, synchronous or not, other skin areas can be utilized for reproducing a nipple and an areola on both breasts.
5. Finally, one nipple-areola complex can be utilized to reconstruct two of the same—a so-called twinning procedure.

6. Personally, I recommend the harvesting and banking procedure whenever possible and transplanting it on the breast three months following chest wall augmentation (Figure 5).

D. Chemotherapy

Chemotherapy per se is no contraindication to breast reconstruction.[21] Not only is the patient monitored by routine blood tests but the type of drugs administered can be varied by dosage interval and selection.

E. Radiation Therapy

If postop radiation therapy is employed, surgery is delayed until eight weeks after treatment cessation.[3 7 15]

F. Skin Flaps

The skin flaps created at the time of mastectomy should be left as thick as possible and consistent with a "complete" cancer operation. Likewise, excessive and luxurious skin excision should be avoided when possible but still meeting the requirements of complete cancer ablation. Excessive amounts of skin are more often removed with huge, pendulous breasts than in smaller, nonptotic breasts.[14]

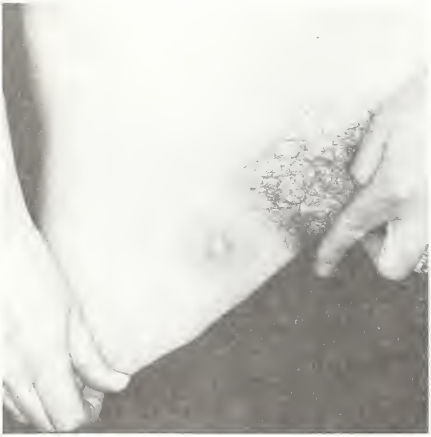

Figure 5
Nipple-areolar graft "banked" in right inguinal area.

V. Perspectives of the Opposite Breast

1. The High Risk Female

The most frequent antecedent of cancer of one breast is the history of cancer in the opposite breast.[22] The exact incidence of patients who develop a second mammary cancer varies between 1%-12% with a median figure of 7%.[23] One study yielded a 14%-20% incidence of synchronous, mirror image bilateral cancers.[24] For the patient under fifty years of age with Stage I disease and perhaps a familial history of breast cancer, simple mastectomy should be considered, especially since the observed incidence of cancer in the second breast in the under fifty age group is seventeen times the normal incidence[25] (Figure 6).

The following are other strong indications for prophylactic simple mastectomy or subcutaneous mastectomy and reconstruction of the opposite noncancerous breast:[1 25 26]

A. Severe, progressive or multiply biopsied fibrocystic disease (Figure 7).

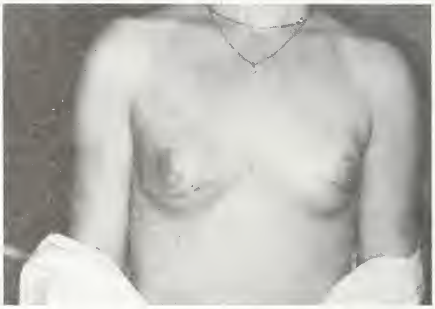

Figure 6
Forty-five year old patient following bilateral breast reconstruction with silicone-gel implants and bilateral nipple-areolar formation from one "banked" complex. Patient underwent modified left radical mastectomy and delayed right simple mastectomy.

B. Intraductal papillomatosis (10% incidence of subsequent cancer).

C. Familial breast cancer (Figure 7).

D. Suspicious or positive mammograms without gross clinical findings.

E. Lobular carcinoma in situ.

F. Parenchymous irregularities resulting from biopsies or infections.

Simple mastectomy[27] is personally favored now over subcutaneous mastectomy for the following reasons:

A. All breast tissue is not removed by subcutaneous mastectomy and this technique can not be considered cancer preventative.[28 29 30] However, in 1940, Hicken[9] stated that simple mastectomy via a transverse incision (Figure 8) is frequently attempted but complete removal of mammary tissue seldom accomplished unless the following technical details are fulfilled:

i. Thin flaps.

ii. Reflect flaps to expose axilla, sternum, epigastric notch and anterior border of latissimus dorsi muscle (Figure 9).

B. The complication rate following subcutaneous mastectomy has been reported to be 28% at Vanderbilt[31] and 59% at Johns Hopkins.[32]

2. The Low Risk Female

A. Remodeling the Other Breast

Reduction of the remaining breast should always be considered not only for cancer prophylaxis but also to match the size of the reconstructed breast.[36] To dupli-

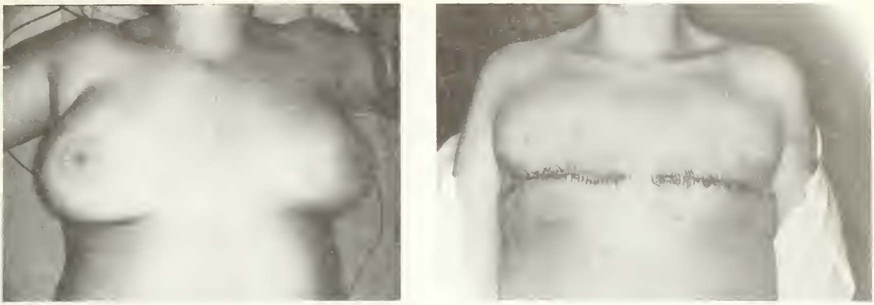

Figure 7
Twenty-eight-year-old, white, single female with bilateral fibrocystic disease and familial breast cancer trait—mother: bilateral breast cancer.
maternal aunt: breast cancer, unilateral
maternal aunt: breast cancer, bilateral.
maternal grandmother: breast cancer, unilateral.
maternal great aunt: breast cancer, bilateral.
Left—preop.: *Right*—postop bilateral simple mastectomies.

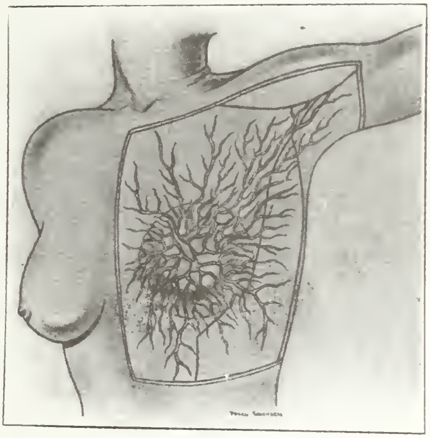

Figure 8
Diagrammatic illustration of the extent of mammary tissue removal required to complete a total simple mammary glandectomy (after Hicken).

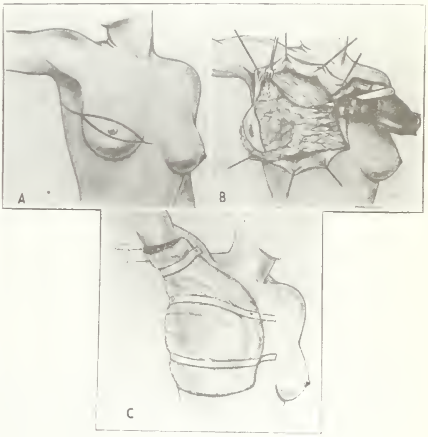

Figure 9
Type of incision-excision recommended for total simple mastectomy (after Hicken). More extensive excision may be required in modified radical mastectomy, but incisional axis is same.

cate the size of the reconstructed breast and to create a firm breast which can withstand the force of gravity, the reduction should be thoroughly radical for technical reasons and cancer prophylactic reasons. This is especially important, since due to the lack of skin and the presence of solid fibrotic envelope which is adherent to the chest wall, the opposite reconstructed post mastectomy breast never shows any sagging. On the contrary, it shows a tendency to migrate upwards in some cases.

If reduction of the normal breast is not contemplated, repositioning the breast to a higher level can be performed using a variety of skin envelope nonundermining ptosis procedures. Occasionally, this breast requires augmentation with a silicone gel implant for equalization of volume.

Conclusion

The perspective for surgically treating female breast cancer has risen above the horizon of Halstead to the broader view of individualizing this type of surgery.

The continual flow of scientific data can boggle the mind and immobilize the surgeon. As this article was being completed, two new papers were published that can contribute to the confusion of not only the general surgeon but also of the plastic surgeon.

For example, when cases of female breast cancer that were not centrally located, not 3 cm. or more in size, and clinically did not involve the nipple were *excluded,* it was microscopically determined that in 39% of the cases studied, cancer was still observed at the nipple or in the upper 6-7 mm. of the areola or both.[37] Does this mean we never transplant a nipple-areola graft?

In another study, foci of cancer (1 mm. or less) were found in almost half of the cases of fibrocystic disease when the total breast tissue was specially studied after subcutaneous mastectomy.[38] Should this be interpreted as meaning that all cases of fibrocystic disease require simple but total mastectomies?

Thus, it is imperative that the surgeon performing breast surgery remain decisive but not dogmatic.

Acknowledgement

I wish to thank Dr. Orlando Pelliccia, Vice Chairman, Department of Surgery and Chief, Section of General Surgery, Hospital of St. Raphael, New Haven, Connecticut for his enthusiasm and encouragement regarding post mastectomy reconstruction at the Hospital of St. Raphael.

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Computerized Tomography in Evaluation of Cushing's Syndrome

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WILLIAM HILLIS, M.D. AND ROBERT D. NEWMAN, M.D.

ABSTRACT—The present case illustrates the use of multiple modalities in evaluating a patient with Cushing's syndrome. The importance of computerized tomography (CT) is emphasized.

Case History

A 61-year-old white female was admitted, 3/8/79, with a history of facial puffiness, hirsutism and easy bruisability for approximately three years. The presence of Cushing's syndrome had been suspected in 1976 at which time the laboratory studies (Table I) were borderline. Hypertension and hyperglycemia were noted approximately one year prior to the present admission. A preadmission evaluation (Table II) revealed an elevation of urinary free cortisol and lack of adrenal suppression to an overnight dexamethasone suppression test. The patient was noted to be obese with relative sparing of the extremities; the skin was dry and mildly pigmented; the facies was rounded with minimal downy hair excess over the chin, lips and preauricular regions. Blood pressure 128/88, pulse 76/minute and regular, respirations 20/minute, temperature 98.6°F, and weight 156 lbs. Full dexamethasone suppression was undertaken at 2 mg and 8 mg levels (Table III) confirming the lack of suppressibility of adrenal cortical hyperfunction.

Table I

BASELINE STUDIES (9-76)

WBC nl SMA nl K 4.2 mEq./1
8:00 a.m. cortisol - 27 ugs % (7-25)
Overnight dexamethasone suppression - cortisol 17 ugs % (L5)
17 - OH - 5.2 mgm (2-6)
Urinary free cortisol 72 ugs (10-90)
2 mg dexamethasone (3 days) - cortisol 8 ugs %

Table II

PREADMISSION STUDIES (2-79)

WBC 11,400 BS 152 mg % (nonfasting)
K - 3.2 mEq./1 (on chlorthalidone)
4:00 p.m. cortisol 23 ugs % (2-9)
Overnight dexamethasone suppression - cortisol 30 ugs % (L5)
17 - OH - 10.8 mg (2-6) 17 ketos - 9.0 mg (6-11)
Urinary free cortisol - 468 ugs (10-90)

Table III

DEXAMETHASONE SUPPRESSION TEST

	17 - OH	*Cortisol*
Baseline	10.8 mg	
Day 1 (2 mg)		32 ugs %
Day 2 (2 mg)	7.1 mg	
Day 3 (8 mg)		19 ugs %
Day 4 (8 mg)	9.3 mg	32 ugs %
ACTH (Baseline)	14.6 pgs/ml (0-80)	

An abdominal CT was performed (Figure 1) demonstrating a right suprarenal mass estimated at several centimeters in size with a clear delineation of a normal appearing left adrenal. The hepatic parenchyma appeared normal in density without evidence of fatty deposition. As a confirmatory step the patient underwent a nuclear medicine localization of increased right suprarenal activity utilizing radioiodinated cholesterol (1.3 mCi 131-6-iodomethyl-10-norcholesterol intravenously with daily oral Lugol's solution coverage for 14 days begun on the day preceding administration of the radioisotope), imaged posteriorly with the gamma camera at 96 hours (Figure 2).

Abdominal exploration was performed, 4/6/79, with a preoperative diagnosis of right adrenal adenoma. At surgery an enlarged right adrenal was encountered and resected with the finding of an approximately 2.5 cm nodular yellow-brown mass, pathologically consistent with an adrenal cortical adenoma (Figure 3). The postoperative convalescence was uneventful with subsequent abatement of Cushingoid features clinically.

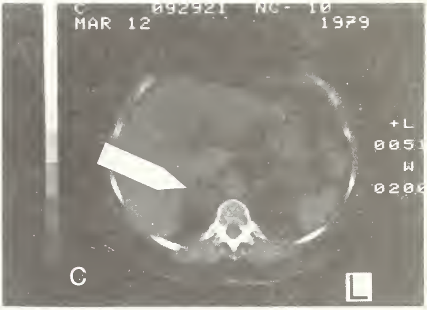

Figure 1
Transverse image illustrating enlargement of the right adrenal (arrow) cephalad to the superior pole of the right kidney.

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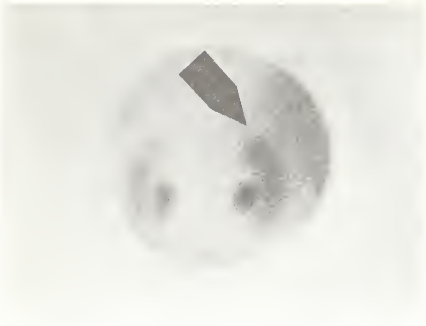

Figure 2
Nuclear medicine scan: posterior gamma camera image with radioiodinated cholesterol (1.3 mCi) superimposed upon supplementary posterior gamma camera image for renal localization (4.5 mCi 99m DTPA) relating the increase of radioiodinated cholesterol to the right suprarenal region (arrow).

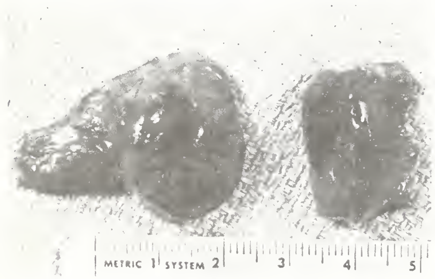

Figure 3
Operative specimen weighing 7.6 gm which is the resected right adrenal gland. It contains an approximately 2.5 cm mass, an adenoma, that compresses the adjacent normal adrenal tissues.

Discussion

At present computerized tomography (CT) is the non-invasive procedure of choice for evaluating adrenal neoplasia, whether functional or not. In patients with Cushing's syndrome, approximately 1 in 6 have either an adrenal adenoma or adrenal carcinoma which are suspected with a high degree of accuracy based upon preliminary biochemical determinations.[1] Since the adenoma or carcinoma is unilateral usually, an important presurgical requisite is localization for which CT is now the most consistently accurate and available non-invasive technique.[2,3,4,5] The use of serial transverse images with small image increments (1.0 cm) and fine collimation (5-10 mm) as well as decreased scan time have improved spatial resolution for depicting adrenal morphology with CT.

Heretofore, reliance was placed on the invasive and technically difficult procedures of adrenal arteriography and venography with sampling which are now relegated to "back-up" roles in confusing and difficult cases as are the presently available competitive non-invasive procedures of ultrasound and adrenal scintography.

Ultrasound is capable of depicting adrenal morphology but is not as consistently obtainable, especially in the heavyset individual, even in experienced hands; ultrasound may be, however, the non-invasive procedure of choice in the uncooperative or thin patient referred for evaluation of a possible suprarenal mass.

Adrenal imaging with the currently available iodinated cholesterol radionuclides provides an accurate means of evaluating adrenal neoplasia in patients with Cushing's syndrome as well as hyperaldosteronism,[6] however, the availability of the radioisotopes is limited and the procedure is time consuming, requiring several days for completion.

CT may be of confirmatory value in adults with Cushing's syndrome, approximately two-thirds of whom have undergone bilateral adrenal hyperplasia secondary to either pituitary adenoma or pituitary hypothalamic dysfunction with such patients showing diffusely enlarged glands without a unilateral mass.

Summary

The present case illustrates the use of abdominal CT as the initial and prime non-invasive procedure for evaluation of the patient with Cushing's syndrome suspected of having an adrenal adenoma. It is noted that the surgeon felt the preoperative localization of the abnormal cortisol production to the right suprarenal region was a requisite to safe and efficient exploration in a heavyset individual in whom obesity obscured the retroperitoneal structures.

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Tuberous Sclerosis Associated with Chylothorax

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EDWARD DUNN, M.D.

ABSTRACT—The pulmonary lesions of tuberous sclerosis and lymphangiomyomatosis have been differentiated to some degrees on the presence or absence of chylothorax. The combination of tuberous sclerosis with chylothorax is extremely rare with only two cases previously reported. We present a third case with lesions strongly suggestive of both conditions and suggest the association of these two entities.

The absence of chylothorax has been historically cited as differentiating tuberous sclerosis from the similar histological picture of pulmonary lymphangiomatosis. Recently we have seen a case of tuberous sclerosis in association with chylothorax.

Case Report

Patient: J.B., a 27-year-old mentally retarded female who in 1973 developed a right pleural effusion. Thoracentesis at that time revealed a chylothorax. She was treated in another institution with frequent chest aspiration until there was no further recurrence of her effusion. In January, 1974, she was readmitted with recurrent chylothorax for which a right thoracic duct ligation and decortication were performed. Postoperatively, she did well but she was seen on January 18, 1977 in our institution with a history of cyanosis and a temperature of 40.2°C. Chest x-ray revealed a left sided pneumothorax.

Physical examination revealed a young, white female with severe mental retardation. There was a cutaneous eruption over the nose and both zygomatic areas. Heart sounds were normal without murmurs. Chest: hypertympanitic to percussion over the left with diminished breath sounds. Spine revealed marked scoliosis. Extremities: subungual fibromas of the toes were noted.

Laboratory workup on admission included a normal urinalysis, white count of 10.7×10^3 with 57 segmented neutrophils, 4 non-segs, 21 lymphocytes, 2 basophil, 1 eosinophil, and 15 monos. The hematocrit was 38.6, hemoglobin 13.4 grams; SMA-12 revealed sodium 143, potassium 4.1, chloride 109, CO_2 21.1, total protein 7.1, albumin 3.9, globulin 3.2, calcium 8.9, glucose 72, urea 16, creatinine 1.2.

Chest x-ray on admission revealed marked deformity with kyphoscoliosis of thoracic cage. A left pneumothorax of about 50% was seen, with chronic blunting of both lung bases. EKG on admission revealed diffuse non-specific ST-T wave changes compatible with myocardial disease. IVP was normal.

Hospital Course

At admission a chest tube was inserted in the left second interspace for relief of her pneumothorax. Approximately 350cc of milky fluid were drained daily for the first several days, gradually diminishing, with a total of 1300cc drained by the 7th day when the chest tube was removed. Examination of the fluid revealed no malignant cells. Specific gravity was 1.030. The fluid was loaded with neutral fat and contained triglycerides 495 mg%, cholesterol 100 mg%, protein 3.3 gm%, and glucose 88 mg%.

Two days following removal of the chest tube the pneumothorax recurred. A tube was reinserted and approximately 150cc of chylous fluid removed. It was removed 5 days later without any further recurrence of her pneumothorax or chylothorax to the present.

Discussion

Bourneville first used the term tuberous sclerosis in 1880 to describe the brain lesion of a severely mentally retarded boy who suffered from epilepsy. In 1908, Vogt established the relation between tuberous sclerosis and facial lesions (adenoma sebaceum previously described in 1890 by Pringle).

Tuberous sclerosis is a rare entity characterized by the triad of mental deficiency, adenoma sebaceum and epilepsy. The patients are usually women between the

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ages of 19 and 49; a familial history usually may be elicited. The disease is systemic and the detailed manifestations will not be described here, having been done elsewhere.[1]

However, chylothorax is an extremely rare symptom having been reported in only 2 cases.

Tuberous sclerosis has certain similarities with another uncommon entity, pulmonary lymphangiomyomatosis. Patients with this disease are also female, ages 14 through 47, but do not have a history of mental retardation with seizures. However, there is a high incidence of chylothorax and pneumothorax (27 out of 34). A detailed review of it has been recently published.[2]

Because of the similarities of the pulmonary lesions of these two uncommon entities, the question of possible relation has arisen. The single major discrepancy between the pulmonary manifestations appears to lie in the presence or absence of chylothorax.

Chylothorax is a prominent feature of lymphangiomyomatosis while only two cases have been reported in patients with tuberous sclerosis.[3 4]

The etiology of pneumothorax and chylothorax is based on the irregular muscular hyperplasia involving the bronchioles and lymphatics with obstruction leading up to lymph-trapping resulting in pneumothorax and chylothorax.

Our patient had the typical tuberous sclerosis triad of mental retardation, seizures, and adenoma sebaceum. She also had subungual fibromas of the toes, pathognomonic of tuberous sclerosis.[5] Also, however, she presented with chylothorax and pneumothorax, more commonly associated with pulmonary lymphangiomyomatosis.

Following insertion of chest tubes and re-expansion of her lung, x-rays showed a diffuse advanced reticular pattern. The chemical composition of the pleural fluid was that of chyle, i.e., a high fat content and protein content approximately 1/2 that of plasma with a high specific gravity.

Unfortunately, there is little to offer patients with tuberous sclerosis therapeutically other than symptomatic treatment. The treatment of this patient's chylothorax included drainage, the use of a fat-free high protein, high carbohydrate diet and replacement as needed of proteins, electrolytes, and vitamins.

Historically surgical intervention in the form of thoracic duct ligation or obliteration of the pleural space has given temporary relief but there have been reported instances of worsening of symptoms and even death.[2 6]

Pulmonary lymphedema and chyloptysis may also develop following surgical interruption of the thoracic duct. Further increasing parenchymal congestion has been observed following therapeutic obliteration of the pleural space.[2 6]

In the case presented, thoracic duct ligation and pleural obliteration controlled the disease on the right side, but the patient returned with a left pneumothorax and chylothorax which up to the present time has been satisfactorily treated by aspiration without further recurrence.

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Foodborne Disease Outbreaks in Connecticut During 1977 and 1978

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A foodborne outbreak is defined by the Connecticut Department of Health Services and the Center for Disease Control as: One case of botulism, one case of chemical poison ingestion, or an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness.[1] Investigations of these outbreaks originate when the public or in some cases, physicians report a food-acquired illness to the local director of health or State Department of Health Services. Follow-up on these cases is handled as a joint effort by the local health department, the State Department of Health Services and in some cases, the Center for Disease Control.

Table 1

FOODBORNE DISEASE OUTBREAKS AND CASES, BY ETIOLOGY
CONNECTICUT 1974-75

Etiology	*Outbreaks*		*Cases*	
	No.	*%*	*No.*	*%*
Bacterial				
Clostridium perfringens	7	30%	247	57%
Salmonella spp.	5	28%	159	37%
Staphylococcus sp.	1	6%	12	3%
Parasitic				
Trichinella spiralis	4	22%	10	2%
Chemical				
Mushroom Poisoning	1	5%	6	1%
Total Known Etiology	18	100%	434	100%
Unknown Etiology	20		540	
	38		974	

This report is concerned with the 38 outbreaks, 837 cases of foodborne illness reported to the Connecticut State Department of Health Services in the two years, January through December 1977-1978 (Table 2). These years differ little from 1974-1975 when 38 outbreaks and 974 cases were reported.

Foodborne disease outbreaks are divided into two categories: First, *Laboratory confirmed*—outbreaks in which laboratory evidence of a specific etiologic agent is obtained; and second, *Undetermined etiology*—outbreaks in which epidemiologic evidence implicates a food source but adequate laboratory confirmation is not obtained. This latter category is divided into four subgroups by incubation period of the illnesses: (a) less than 1 hour (suggestive of chemical etiology), (b) 1 to 7 hours (suggestive of *Staphylococcus*), (c) 8 to 14 hours (suggestive of *Clostridium perfringens*), and (d) greater than 14 hours (suggestive of other agents such as *Salmonella,* etc.).[1] These rough temporal criteria require support of other epidemiologic evidence due to the overlapping of incubation periods.

The incubation period of *C. perfringens* foodborne illness is usually between 8 to 14 hours with a range

Table 2

CONFIRMED FOODBORNE DISEASE OUTBREAKS AND CASES,
BY BACTERIAL AND NON-BACTERIAL ETIOLOGY
CONNECTICUT 1977-78

Etiology	*Outbreaks*		*Cases*	
	No.	*%*	*No.*	*%*
Bacterial				
Clostridium perfringens	1	11%	45	15%
Salmonella spp.	4	44%	266	74%
Staphylococcus sp.	2	22%	17	5.6%
Bacillus cereus	2	22%	16	5.3%
Total Known	9	100%	304	100%
Unknown	29		533	

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from 5 to 24 hours. The primary symptoms are moderate to severe abdominal cramps and watery diarrhea. Nausea has been reported in 30% to 50% of patients and vomiting in up to 10%. Headache, fever and chills are not usually present.[2]

The absence of fever may differentiate *C. perfringens* foodborne disease from shigellosis and salmonellosis, while the low frequency of vomiting and longer incubation period are in contrast to the clinical features of staphylococcal and chemical foodborne diseases.[2]

The incubation period of staphylococcal foodborne illness is usually 2 to 4 hours, (range ½ to 7 hours). Onset of illness is usually abrupt and is characterized by nausea, vomiting and abdominal cramps followed shortly by diarrhea. Feverish feeling and chills have been reported in approximately 20% of outbreaks, but in most instances fever has not been documented, contrary to salmonellosis which has the tendency to produce a temperature of 100.4-102.2°F. Along with the fever in salmonellosis, nausea and vomiting are common initial symptoms, but are rarely as prominent as the colicky abdominal pain and diarrhea. The incubation period for salmonellosis is usually 8-24 hours (range 6-48 hours).[3]

Table 3

FOODBORNE DISEASE OUTBREAKS BY PLACE WHERE MEAL WAS PREPARED

Place	*Outbreaks*		*Cases*	
	No.	*%*	*No.*	*%*
Restaurant	22	57%	345	41%
Delicatessen	1	3%	4	.5%
Picnic	2	5%	16	2%
Private Home	7	18%	273	33%
Hospital & Institution	3	8%	50	6%
School	2	5%	147	18%
Other	1	3%	2	.2%
	38		837	

Recent data indicate there are two distinct clinical forms of *Bacillus cereus* food poisoning. One, the emetic form associated with contaminated fried rice, has a short incubation period and is characterized by predominantly upper gastrointestinal tract symptoms, rather like staphylococcal food poisoning. The other, the diarrhea form, has a long incubation period and is characterized by predominantly lower-intestinal tract symptoms, as in *Clostridium perfringens* food poisoning.[4]

Outbreaks of *Bacillus cereus* with rapid onset are associated with rice, and those of longer onset with puddings, sauces, meat combinations and bean sprouts.[4]

Other foodborne pathogens include *Clostridium botulinum* whose incubation period is 12 to 48 hours but can range from 6 hours to 8 days. Initial symptoms include nausea, vomiting or constipation. The primary clinical features of the disease are neurologic.

Vibrio parahaemolyticus has been diagnosed as foodborne disease pathogen in Connecticut in previous years. The incubation period of *V. parahaemolyticus* gastroenteritis usually ranges from 12 to 24 hours; however, incubation periods as short as 4 hours and as long as 60 hours have been reported. Two distinct clinical syndromes are associated with this disease. In the more common syndrome, patients experience explosive watery diarrhea, abdominal cramps, nausea, and vomiting; fever and chills can occur but are less common. The other clinical syndrome is a dysentery-like illness characterized by acute abdominal pain, diarrhea, stools with gross blood and mucus, and fever.[2]

Table 4

FOODBORNE DISEASE OUTBREAKS OF UNKNOWN ETIOLOGY BY MEDIAN INCUBATION PERIOD. CONNECTICUT 1977-78

Incubation Period in Hours	*Outbreak*		*Cases*	
	No.	*%*	*No.*	*%*
1	1	4%	142	27%
1-7	5	17%	33	6%
8-14	8	28%	123	23%
14	1	4%	12	2%
TOTALS	29	100%	533	100%

The Food Service Sanitation Manual describes potentially hazardous foods as any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shell-fish, edible crustacea, or other ingredients, including synthetic ingredients, in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.[5] The term does not include foods which have a pH level of 4.6 or below or a water activity (Aw) value of .85 or less. As indicated by this definition practically any food, under certain conditions, can be potentially hazardous.

In the most recent statistics, 1976, nationwide the majority of bacterial cases were caused by *Salmonella* (33%) and *Staphylococcus* (26%).[1] In the state of Connecticut, the majority of bacterial cases included *Salmonella* (74%), *C. perfringens* (15%), *Staphylococcus* and *B. cereus* with 5.6% and 5.3 respectively (Table 2).

These data refer only to outbreaks with a laboratory confirmed etiology and include only 24% of the total foodborne outbreaks in Connecticut for 1977-1978.

Some possible reasons for the low percentile of confirmed outbreaks include inadequate disease surveillance and insufficient foodborne outbreak investigations; production of a small data base may exaggerate Connecticut's statistics resulting in an inconsis-

Table 5

FOODBORNE DISEASE OUTBREAKS BY CONTRIBUTING FACTORS AND ETIOLOGY, CONNECTICUT 1977-78

Etiology	*No. of Out-breaks*	*Im-proper Holding Temp.*	*In-adequate Cooking*	*Poor Per-sonal Hygiene*	*Food from Unsafe Source*
C. perfringens	1	1	1	0	0
Salmonella sp.	4	4	2	1	1
Staphylococcus sp.	2	0	0	0	9
B. cereus	2	2	1	0	0
Unknown	29	12	3	4	4
Total	38	19	7	5	5
Percentage of total for which factors were reported—		86%	32%	23%	23%

tency between Connecticut and the nationwide statistics. However, Connecticut also has a comprehensive salmonella surveillance system with required reporting and follow-up. This reporting system could be the reason for Connecticut's 74% confirmed salmonella compared to 33% nationwide.

In 1976, restaurants and private homes were the suspected sources of 65% of the total outbreaks and similarly, 75% of 1977-78 outbreaks being attributed to those sources.

Improper holding-temperatures were a contributing factor in 86% of the outbreaks and inadequate cooking was a contributing factor in 32% of foodborne outbreaks. These two factors indicate a lack of awareness of the time/temperature relationship in food preparation (Table 5).

It is likely that the majority of foodborne illness is not recorded, or if recorded, not reported to the State Department of Health Services. Public Health Code Section 19-13-A2 of the State of Connecticut requires foodborne outbreaks be reported within 24 hours to the local health department by telephone and to the local and state health departments on the Communicable Disease Report form. Under Connecticut General Statute 19-18, it is the responsibility of the state or local health department to institute and cooperate in the investigation of foodborne outbreaks. However, the state or local health departments are not capable of performing their investigation and preventing a subsequent outbreak if they are not kept informed by the physicians.

Effective control of foodborne diseases depends on prevention of factors that contribute to the occurrence of foodborne disease outbreaks. Prevention, however, will not be achieved without the full cooperation of all persons involved in the handling and processing of food. This includes public health people on the educational level, food managers on the business level, food handlers on the preparation level, doctors on the medical level, and of course, the general public's own awareness of food preparation procedures.

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The Primary Head and Neck Manifestations of Myasthenia Gravis and Amyotrophic Lateral Sclerosis: A Diagnostic Aid

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ABSTRACT—Myasthenia Gravis and Amyotrophic Lateral Sclerosis are neuromuscular diseases of insidious onset that may present primarily with symptoms relating to the Head and Neck with latter involvement of the lower motor neurons. The physician should be aware of this presentation in the differential diagnosis of these entities.

Introduction

Myasthenia Gravis (MG) and Amyotrophic Lateral Sclerosis (ALS) are neuromuscular diseases of insidious onset involving upper and lower motor neurons.

Myasthenia Gravis involves voluntary musculature and is manifested by fluctuating weakness and fatigue made worse by exertion or stress with partial recovery of muscle strength after a period of rest. The muscles innervated by the cranial nerves are involved early in the disease with ocular symptoms prevailing. The cause of MG is unknown. Possible factors include a defect in the synthesis or release of acetylcholine at the neuromuscular junction, a disturbance in polarization of the muscle-fiber membrane, or a circulating neuromuscular blocking agent secondary to a viral infection or an autoimmune process. Recent studies have documented anti-receptor and anti-muscle antibodies in a majority of patients, however, no specific immune deficiency has been found.

Amyotrophic lateral sclerosis is characterized by progressive degeneration of motor units. The disease manifests itself as progressive muscular atrophy, lateral sclerosis, and pseudobulbar and bulbar palsy in various combinations. In the classic presentation of ALS, progressive muscular atrophy in the extremities is the common mode of onset. Initial complaints are of weakness, fasciculations, and cramping. Involvement of the pyramidal tracts, or lateral sclerosis, is a rare initial complaint but appears later in the course of the disease, with progressive spasticity and hyperactive reflexes. With brain stem involvement, pseudobulbar palsy may ensue with findings of a positive sucking reflex and possible unprovoked emotional outbursts. Bulbar palsy is secondary to involvement of the cranial nerve musculature. Classically, this is a terminal event, but it may be an initial complaint in more than one fourth of the patients.

Findings

Myasthenia Gravis: Most cases of MG were diagnosed in patients in the sixth, seventh, or eighth decade of life. Primary symptoms are listed in Table I.

On physical examination, muscular weakness was the most common finding. Weakness of the orbicularis oculi muscles was demonstrated in more than 75% of patients, irrespective of presenting symptoms. Fluctuating muscle weakness, noted in most patients, was documented by a positive response to administration of edrophonium chloride (Tensilon) and by electromyography.

Electromyography was done as a part of the diagnostic workup in most patients. The observation of a defect in neuromuscular transmission with stimulation and repair of the defect after a period of rest supported the clinical impression of myasthenia gravis.

Table I

PRIMARY CRANIAL NERVE SYMPTOMS OF MYASTHENIA GRAVIS

	Patients			
Symptoms	*No.*		*Percent*	
Ocular		99		57
Diplopia	45		26	
Ptosis	36		21	
Both	18		10	
Oral, pharyngeal, and laryngeal		53		30
Dysphagia	27		15	
Dysarthria	22		13	
Dysphonia	4		2	
Others		33		13
Weakness of muscles of mastication	11		6	
Facial weakness	8		5	
Neck weakness	2		1	
Dyspnea	2		1	

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Most patients presenting with articulatory or palatopharyngeal symtoms underwent speech examination (Table III). The observation of fatigue and weakness of articulation, deterioration of articulation with prolongation of sounds, nasal emission and hoarse or breathy phonation with repair after rest was helpful in the diagnosis.

Amyotrophic Lateral Sclerosis

The average age of the 123 patients diagnosed as having ALS was 61 years, with a range of 33 to 81 years.

The sites of the primary symptoms are listed in Table II. Twenty-six percent of the patients had later symptoms involving the extremities. These symptoms were equally distributed between upper and lower extremities and weakness was the complaint in 70% of these patients. Other symptoms were fasciculation, cramping, atrophy, and feelings of numbness, although results of sensation testing were always normal.

On physical examination, muscular weakness was the most common finding. Tongue weakness, demonstrated by slowed alternate-motion rate and poor tongue protrusion, was documented in 81 patients (66%), irrespective of presenting symptoms. Extremity weakness was another common finding, even though many patients did not mention such weakness as a symptom (66%). Other muscle groups involved were the sternomastoid and trapezius muscles innervated by the accessory nerve (41%), the facial musculature innervated by the glossopharyngeal and vagus nerves (23%), and the muscles of mastication innervated by the trigeminal nerve (8%). Another prominent physical finding was muscle fasciculation, which most often involved the tongue (54%) or the extremities (30%).

Most patients had an electromyogram (EMG) as a part of the diagnostic work-up. The observation of fasciculation potentials (sporadic spontaneous muscle activity), denervation of whole motor units with fibrillation potentials, and reduction in the number of action potentials during voluntary contraction supported the clinical diagnosis of ALS and helped to verify the distribution of the disease.

Table II

PRIMARY CRANIAL NERVE SYMPTOMS OF ALS: SITES OF INVOLVEMENT, MANIFESTATIONS, AND PATIENTS' COMPLAINTS

Site	*% of Patients*	*Manifestation*	*Complaint*
Tongue	68	Slurred speech	Thick speech Slow speech Nasal speech "Like a drunk" "Can't whistle" "Hard to move tongue"
Vocal cords	14	Hoarseness	Voice Change Weak singing voice
Esophagus and pharynx	13	Dysphagia	Choking Aspiration Regurgitation
Respiratory tract	3	Dyspnea	
Neck	1	Neck weakness	
Jaw	1	Jaw weakness	Difficulty chewing

In many patients with dysphagia, contrast studies were performed to rule out the possibility of other pharyngeal or esophageal lesions. Barium swallow and esophageal motility studies aided in diagnosis by demonstrating spontaneous and repetitive contractions, lack of coordination during swallowing, and decreased sphincter resting pressures in an anatomically normal gullet.

During the follow-up period, muscle weakness and atrophy progressively involved both bulbar and spinal musculature in all patients. Involvement of the muscles of respiration with dyspnea, aspiration pneumonitis, and respiratory failure was a terminal event.

Discussion

The first description of the syndrome of myasthenia gravis is credited to Thomas Willis in 1672.[1] Jolly introduced the disease entity as "myasthenia gravis pseudoparalytica" in 1895.[2] In 1901, Laquer and Weigert associated thymic tumor and myasthenia gravis with gross and microscopic findings.[3]

The symptoms of myasthenia gravis are secondary to muscular weakness and generally are intermittent and fluctuating. Ocular symptoms prevail in most patients. Some patients may have a limited form of the disease, with only ocular symptoms and no progression to other muscle groups. Diplopia presents asymmetrically and usually involves upward, medial, and lateral gaze. Ptosis is also common and may present as a transient unilateral weakness of the orbicularis oculi muscle of fluctuating severity.

The other common complaints in MG patients are dysphagia, dysarthria and dysphonia. These problems may bring the patient to the physician with complaints of difficulty swallowing, choking, regurgitation, or changes in speech with continued talking.

The association of progressive muscular atrophy and sclerosis of the lateral column was first described by Charcot in 1868.[4] Before this time, Duchenne in 1849 and Aran in 1850 had described the condition of progressive muscular atrophy and in 1860 Duchenne had added the clinical description of progressive bulbar palsy.[5,6,7] More recently, Charcot's original concept of ALS has been broadened to include a spectrum of neuromuscular disease from progressive bulbar palsy, the wasting of muscles innervated by cranial nerves to primary lateral sclerosis, spasticity, and hyperreflexia without muscle wasting, although the entity primary lateral sclerosis rarely evolves into generalized ALS.

There is no single diagnostic test for ALS. Diagnosis is based on the history and physical examination supplemented by electromyography. Speech pathology examination and esophageal motility studies are helpful in many cases. More than one fourth of the patients in this series were seen initially with bulbar palsy and progressive and unremitting complaints of slurred speech (68% of patients), hoarseness (14%) and dysphagia (13%).

In the diagnosis of oral, palatal, pharyngeal, or laryngeal weakness, it is useful to think of the upper airway as composed of three separate levels: articulatory (lips, tongue, and mandible), velopharyngeal (palate and pharynx), and phonatory (larynx). (Table III) Articulatory difficulties are secondary to weakness of the lips, tongue, or mandible. With facial weakness, the lips are affected; this causes problems with the production of bilabial consonants (b, m, and p). Tongue weakness slows the articulatory rate, and speech becomes labored and imprecise. Examination of the tongue at this time may show a slow alternate-motion rate and, in the patient with ALS, atrophy and fasciculations. The patient may be unable to protrude his tongue or to touch his palate with his tongue. Drooling may be noted.

Table III

SYMPTOMS OF DYSARTHRIA AND DYSPHONIA

- Articulatory (lips, tongue, mandible)
  - Fatigue, weakness
  - Imprecise articulation
  - Deterioration with prolonged articulation
  - Return to normal after resting
- Palatopharyngeal
  - Nasal emission (hypernasality)
- Laryngeal
  - Weakness
  - Hoarseness
- Breathy phonation
- Decreased loudness
- Fatigue with prolonged articulation

Palatopharyngeal weakness allows nasal emission of air during speech; this results in hypernasality. Consonant sounds, which depend on intraoral pressure, become weak. Nasal regurgitation of liquids also may occur. Nasal emission may be sought during speech by placing a cold laryngeal mirror close to the patient's nose and having him repeat "we see three geese" or any group of words lacking the letters "m," "n," and "ng," which normally require nasal emission for formation.

Weakness of pharyngeal musculature is manifested by dysphagia for liquids or solids, with choking when the glottis is incompetent. It may be intermittent, of varying degrees, and worse with either solids or liquids.

With MG, laryngeal involvement produces a fluctuating dysphonia that worsens with prolongation of articulation. Poor adduction of the vocal cords allows escape of air during phonation and results in a breathy or hoarse voice. Sentences are short because weakness and exhaustion are rapid. A weak cough is also present, which results in retained secretions both at the laryngeal level, causing a "gurgly" voice, and in the lower airway. Weak abduction may be more serious, with ensuing stridor and dyspnea. An excellent review of the speech signs in neuromuscular disease has been presented by Darley, et al.[8]

Fatigability should be sought on examination by asking the patient to sustain a muscular action or to perform repetitive tasks. One useful office test is to ask the patient to count backward from 100; fatigue usually begins by the time the patient has counted to 80. Repair of the muscular defect after a period of rest or after administration of anti-cholinesterase medications (Tensilon test) is essentially pathognomonic of myasthenia gravis.[9]

Involvement of the laryngeal musculature by ALS produces a dysphonia with both flaccid and spastic components. Hoarseness is the most common laryngeal symptom. Results of laryngeal examination are usually normal.

The diagnosis of ALS should be entertained by patients complaining of changes in speech, dysphonia or dysphagia with associated muscular weakness, atrophy or fasciculations. The ocular muscles are not involved in ALS. Repair of the muscular defect after rest does not occur and the course is one of progressive involvement and weakness of muscle groups.

Summary

Patients with MG or ALS may present with primary bulbar involvement of varying degrees and no peripheral findings. A high index of suspicion is necessary to confirm the diagnosis in these patients.

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The Changing Clinical Presentation of Colo-Rectal Cancer

Introduction

DR. HASTINGS K. WRIGHT (Vice Chairman, Department of Surgery, Yale): Forty years ago the typical patient with colo-rectal cancer was a male in his sixties who presented with rectal bleeding. The diagnosis of his rectal cancer could usually be made with digital examination. Abdominoperineal resection was necessary.

This clinical picture is no longer accurate. Axtell, et al. first noted in the 1960's the trend in the United States toward development of proportionately more colon cancers and fewer rectal cancers.[1] While in the 1940's the ratio of colon to rectal cancers in males in this country was 1:1, by 1960 it had become 1.6:1. The change in females was even more striking, rising from 1.6:1 to 2.4:1 by 1960. Similarly, Rhodes, et al. noted that while in the mid-1940's 82% of colo-rectal cancer was in the sigmoid colon or lower, by 1975 40% of such cancers were higher than the sigmoid colon.[2]

While the textbooks of the 1950's declared that 50% of colo-rectal cancer could be felt on careful rectal examination, by the mid-1970's Berg found that only 12% of colo-rectal cancers could be diagnosed by digital examination.[3] To further illustrate the trend, Abrams, et al. have recently reported the striking finding that 35% of colo-rectal cancer in Vermont is now in the right colon.[4]

Obviously, the clinical presentation of colo-rectal cancer has changed to reflect this new anatomical distribution. Now that rectal examination and sigmoidoscopy no longer will detect most colo-rectal cancer, how well are we doing in diagnosing colon cancers which now occur above this level almost 40% of the time? To answer this question, we asked four south central Connecticut hospitals to find out how many colo-rectal cancers each treated in 1977-1979, and to then analyze their right colon cancers during this period to determine the method of presentation and to correlate this with final pathological staging.

Clinical Data

In this two-year period, 757 cases of colo-rectal cancer were diagnosed in these four hospitals, of which 191 (25%) were the right colon proximal to the hepatic flexure. This finding again emphasizes the high frequency of right colon cancer today.

Of the 191 right colon cancer patients, 135 (71%) presented with symptoms (pain, obstruction, or obvious rectal bleeding) which made a gastrointestinal tract work-up mandatory. However, 56 patients (29%) presented without symptoms. Ten had a mass discovered on routine physical examination, and another ten had occult blood in the stool, with an appropriate GI tract workup being done in each case. Thirty-six patients (19%) presented with only microcytic, microchromic anemia. An appropriate GI tract workup was done initally in only 12 of these patients. A GI tract workup was delayed for *more than a year* in 14 patients until symptoms developed with the patients being treated for the anemia alone with iron by mouth rather than being investigated for the cause of their anemia.

Another cause of delay in treatment was failure in 27 cases of detection of the right colon lesion by the initial barium enema. The initial false negative barium enema usually led to a false sense of security, particularly in asymptomatic patients, and delay in correct diagnosis usually exceeded six months, occurring only when symptoms prompted re-examination.

Finally, the data on tumor staging by Duke's method for these patients showed that two-thirds of the *asymptomatic* patients had right colon cancers limited to the bowel wall. In contrast, only one-third of symptomatic patients had cancers limited to the bowel wall. Since Duke's classification correlates well with five-year survival rates, it is obvious that the asymptomatic patient should be expected to do far better after diagnosis and surgery than the symptomatic patient.

A Panel Discussion at Surgical Grand Rounds, Yale-New Haven Hospital, November 9, 1979.

Panel Discussion

The evidence from the data gathered at these four south central Connecticut hospitals suggests that: 1) right colon cancer is becoming increasingly frequent; 2) it is not being diagnosed as early as it could be in a significant percentage of asymptomatic patients who can be expected to have more curable lesions; and, 3) when a barium enema is carried out, a correct diagnosis is not made on the first attempt in a significant percentage of patients.

We will now ask the panel whether they have any ideas on how we can improve this performance.

First of all, is there any general population surveillance technique which might be used cost effectively in order to pick up asymptomatic patients with carcinoma of the colon?

DR. MICHAEL DEAN (Chief of General Surgery, St. Vincent's Hospital, Bridgeport): To my knowledge there is no group with an increased risk of developing right colon cancer which would be equivalent to the groups of patients with multiple polyposis of the colon or long standing universal colitis, both of whom are at high risk for colon cancer. Certainly we know that women have more right colon cancer than males. If studies now being done in the United States in large, asymptomatic patient populations demonstrated that frequent testing for occult blood in the stool will be a cost-effective method of picking up colon cancer, then this would be a simple surveillance technique.

The data presented today indicate that the asymptomatic patients are found because they have an abdominal mass (which would mean doing routine physical examinations on a systematic basis) or because they have blood loss. When a physician detects asymptomatic iron deficiency anemia, he should look for a site of occult blood loss. It is unfortunate that half of the asymptomatic patients in this series were treated for iron-deficiency anemia thought to be on a nutritional basis by their first physician of contact. Had these physicians realized that iron deficiency anemia is relatively uncommon on a nutritional basis in the United States, and had they looked for a source of blood loss, then these patients would have been picked up earlier. We certainly need to emphasize this fact to the family physician who sees these patients first.

DR. EDWARD DUNN (Chief of Surgery, Waterbury Hospital): There was a recent report by the American College of Surgeons which is somewhat distressing, indicating that the incidence of localized cancer of the colon was exactly the same in patients with symptoms under one month before diagnosis as it was in patients who had had symptoms for over a year.[5] Indeed, the patients who had symptoms for less than a month had only 29% of their tumors localized to the colon wall itself. The present data indicate, in contrast, that the asymptomatic patients have far more localized colon cancers, and some test must be discovered which is cost effective to pick such patients up. I believe that is the only way we are going to increase the survival rate of colon cancer.

DR. WRIGHT: Looking at diagnostic methods used to detect colon cancer, it was distressing to see the large percentage of initial barium enemas which were false negative in patients who actually had right colon cancers. Is there any method which could be used to improve this batting average?

DR. NICHOLAS COASSIN (Chief of Surgery, Milford Hospital): The most important thing to do is to alert the radiologist to the fact that you suspect a proximal colon carcinoma. The radiologist will then go to great lengths to fill out the right colon and the cecum in particular, and not accept a poorly prepared bowel for the study. Secondly, it is extremely important for the clinician who has ordered the x-ray to review the results with the radiologist. Then if there is any suspicion in the radiologist's or the clinician's mind, a repeat barium enema should be performed immediately. I believe that is one method by which one can eliminate most of these false negative x-rays.

Another possibility would be to perform colonoscopy on all patients on whom one has not made a radiologic diagnosis and who still have occult blood in their stool. I think this is probably the method that should be used in 1980 rather than assuming that negative x-rays mean that the patient has no lesion.

DR. WRIGHT: Up to this point we have talked about making a diagnosis. Now we might ask if there is anything new in the treatment of cancer of the right colon?

DR. DUNN: I wish I could say there was something really new, but the only new findings are that rigorous attention to principles will give the best results. The no-touch technique of Dr. Turnbull was very promising a decade ago, but others have gotten equally good results by simply doing wider resections of the right colon. As a consequence, I think that it has been Dr. Turnbull's experience and surgical technique rather than the actual performance of a no-touch operation which has been important. A very encouraging report was presented this fall from the University of Chicago by Enker, Laffer, and Block which showed that en bloc wide resections of either the right or left hemicolon for right and left colon cancer, respectively, gave better results than limited segmental resections alone.[6]

Question: Is there any value in doing CEA levels on patients who have occult blood in the stool as a preliminary screening device?

DR. WRIGHT: This would not be a cost effective technique. The evidence to date suggests that determination of the CEA level will be of help only in patients who have had a carcinoma of the colon resected, followed by fall of the CEA levels to normal, and then a subsequent rise after several months in the normal range. This is good evidence that the patient has had recurrence, and there are studies underway currently to determine whether re-operation at the time of a rising CEA in asymptomatic patients will yield a high re-resectability rate. These studies are still underway, and until they are complete I do not believe that surgeons not contributing patients to these studies should follow such a policy.

Question: It appears that none of these four hospitals are really using colonoscopy frequently in the diagnosis of large colon lesions. Is this a technique which should be adopted increasingly?

DR. COASSIN: We have had increasing experience with colonoscopy, but it has been in the opposite direction than you suggest. Colonoscopy has been very valuable to us in ruling out mucosal lesions in patients who have had suspicious barium enemas with multiple repeat barium enemas not clarifying the situation. In patients that have had bona fide carcinomas, we have not had difficulty making a clinical diagnosis with well-done barium enemas in well prepped patients, although repeat barium enemas have often been necessary.

DR. ARTHUR E. BAUE (Chairman, Department of Surgery, Yale): I would like to ask the panel if they would speculate on why colon cancer is shifting upward from the rectum to the colon, and particularly to the right colon?

DR. WRIGHT: There is no specific answer to that question except for the conviction on the part of epidemiologists that there has been a shift in exposure to a carcinogen or a co-carcinogen which affects the right colon and not the rectum. It seems to be sex related, since there is an increasing incidence of right colon cancer in females compared to males which complicates the situation.

DR. DEAN: There is certainly an increasing incidence of Crohn's disease in the United States. This has now been related statistically to an increased incidence of colon cancer, and it is possible that some of the increase in colon cancer that is being seen in the United States is secondary to very low-grade, unrecognized inflammatory bowel disease.

DR. WRIGHT: It is obvious that we have a long way to go in improving the survival rate of this second most common of all cancers in adults. Much of any future improvement is going to require discovery of a method of making an early diagnosis in asymptomatic patients who have colon cancer. Surgical techniques have about reached their limit of perfection, and I doubt that there will be any further increase in survival recorded because of new technical developments. Finally, if the epidemiologists can discover the hypothesized agent which may be increasing both the incidence of proximal colon cancer and its frequency in females, then we may be able to eliminate that from our diet or environment.

I would like to thank the panel for discussing this problem today, and particularly thank Dr. Seddiq, Dr. Loutfie and Dr. Higgins who, with Dr. Coassin, did all the leg work in the record rooms of these four hospitals in looking up the cases which formed the basis for our discussion today.

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Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A National Institutes of Health Consensus Development Conference on Improving Clinical and Consumer Blood Pressure Measuring Devices was held at NIH on April 26-27, 1979.

The purpose of the conference was to bring together representatives of the medical profession, engineering, consumer groups, and Government in an effort to help develop language for proposed national voluntary guidelines for the use and manufacture of sphygmomanometers—blood pressure measuring devices. At NIH, biomedical research scientists, practitioners, legal experts, industry representatives, consumers, and others, meet at consensus development conferences in an attempt to reach general agreement on the safety and efficacy of medical technologies.

This consensus development meeting was scheduled in view of the recent availability of blood pressure measuring devices to consumers without the existence of guidelines to cover the accuracy and lifespan of the sphygmomanometers or the manner in which the public should use them. Coin-operated blood pressure measuring devices have been introduced to drugstores, airports, and other public locations in the past two years, while "take-home" blood pressure kits have been on the market for approximately three years.

During the meeting, seven workshops dealt with various aspects of proposed national voluntary guidelines and developed recommendations. The topics addressed included scope and labeling, performance requirements, and test methods of validation procedures for either automated or nonautomated sphygmomanometers, and needs of special patients, such as the elderly and children. The Association for the Advancement of Medical Instrumentation draft guidelines for sphygmomanometers served as the focal point for discussions. Following are the key conclusions drawn by the groups:

Workshop A:

This group discussed scope and labeling for nonautomated devices.

The outer container for the sphygmomanometer should be properly labeled to include information needed by the "end-user." Product literature should accompany the device, and it should include a list of precautions. Among these are the manufacturer's recommendations for calibration checks, cleaning and care of the instrument, hazards of prolonged overinflation of the device's bladder, methods for determining malfunctioning of the display device, and, when required, recommended sterilization procedures and methods for dealing with mercury spills.

The literature should include both adequate operating and use instructions, including the need to consult with a physician for interpretation of pressure measure-

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NIH Consensus Development Conference Summary Vol. II, No. 4

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ments. Manufacturers should not attempt to tell an individual how to interpret his or her measurements and, in fact, should be active in encouraging that the user consult with a physician.

Labeling language should require warranty information and identify available service centers. In addition, the cuff should be labeled or prominently marked as to the intended limb diameter or circumference. The size of the cuff has a very important bearing on the accuracy of the reading. It would be very useful to have information on the cuff itself—some means of identifying what particular kind of size limit the device would have.

There was a recommendation to include several terms for definition in the glossary section.

Workshop B:

This group dealt with performance requirements for nonautomated sphygmomanometers.

Any part that is labeled conductive should also be labeled with a precaution that the conductivity is useless if the part is not used with other components that are conductive.

It was generally agreed that instead of relating the width of the bladder to the diameter of the patient's arm, it should be related to arm circumference, which is easier to measure or estimate.

On the aneroid dial, no decision was reached on the method of specifying durability, but the workshop recognized the need to determine that such a method be included in guideline requirements or be included in the guidelines test methods section. It was suggested that on the mercury-gravity manometer, the requirement state that a space below zero be visible so that if the mercury is below zero, there would be a visible reading.

It was agreed for the calibrated tube that a minimum wall thickness as well as a minimum diameter be specified. An alternative would be to have the test methods section cover the breakability of the glass tube. Preferably, language concerning wall thickness and the withstanding of breakage tests should both be included in the guidelines.

It was agreed that the accuracy requirements for manometers, within specified temperature ranges, should be re-examined.

Workshop C1:

This group dealt with test methods or validation procedures for nonautomated sphygmomanometers.

The question of accuracy and system reliability was raised during the discussion of testing. It was the consensus that a test arm for checking the accuracy of nonautomated sphygmomanometers would be of great assistance. There was consensus that there should be some type of life testing of devices to ensure that the consumer does not obtain a device, use it a few times, and then discover that it no longer functions. Such testing should be part of the guideline requirements.

It was suggested that various tests be combined and others be done in sequence so that the test procedures are simplified and follow one another in a more organized fashion.

There was consensus to enter into some type of field testing of clinical accuracy of blood pressure measuring devices. It was also suggested that a statement be included regarding accuracy verification in the labeling of manometers.

It was also suggested that labeling instructions should urge that the blood pressure measuring device be checked against the patient's physician's mercury unit. The label should also suggest that the device be sent back to the manufacturer periodically to ensure that the unit continues to be accurate (i.e., calibrated).

Workshop C2:

This group dealt with scope and labeling of automated/electronic sphygmomanometers.

Participants agreed that the draft scope document was adequate. The group agreed that some additions should be made to the labeling document language.

When the devices are used in a nonclinical setting, a statement should be prominently displayed on the device that states: "For interpretation of results, a physician should be consulted."

A workshop member asked to define "longevity" of devices, but the group agreed that it would be extremely difficult to develop specific language. In order to give users some basis on which to judge longevity, information on product warranty and exclusions should be included in all documentation accompanying sphygmomanometers. In this way, the manufacturer would advise a consumer on how long the warranty period might be.

It would be quite helpful to include a comprehensive glossary with any guidelines in order to be sure everyone is using the same set of definitions regarding use and manufacture of blood pressure measuring devices.

Workshop D:

This group dealt with performance requirements for automated/electronic sphygmomanometers.

Among the items discussed were methods of verifications of operations and concerns about coin-operated blood pressure measuring devices.

Test methods and testing cycles generated considerable discussion. The existing document basically requires only one test—there is no mention of the need for a device to meet the requirements over a certain number of cycles. Such language should be part of any guidelines to ensure that the device has some long-term stability.

There was a suggestion that testing tolerances be changed from "plus or minus" to "ranges greater than and less than." This was urged because the ranges, not the specific numbers, are most important.

The minimum voltage and frequency requirements for line-operated equipment should be reinserted in the proposed guidelines. At present, the proposed guidelines state that these are parametric and specified by the manufacturer.

There was some concern for indicating on coin-operated devices that their ability is limited. It was felt that more data should be present on what possible applications the device is intended for, such as arm size.

Workshop E:

This group discussed test methods of validation procedures for automatic/electronic sphygmomanometers.

Much discussion centered upon the problem of system verification versus the defective instrument. There was some concern that it would be quite helpful if there were a means of verifying in the field if an instrument were working properly. The subject of the use of an artificial arm for testing device accuracy arose. The group agreed that it was not the place of guidelines to require the use of an artificial arm for testing. It might, however, be appropriate that a recommendation for future research state that for design and verification and for field evaluation, such a test arm would be extremely desirable.

Considerable discussion surrounded the three methods of design verification: comparison with the auscultatory technique, comparison against intra-arterial pressure, or comparison against another instrument which has been verified against intra-arterial methods. Several workshop participants considered the verification by auscultatory methods unacceptable. Another group, however, felt this method was to be preferred. In general, the group agreed that all three methods would be acceptable and that the method chosen would depend upon which device was being tested and into which market or usage segment it was placed.

Workshop F:

This group dealt with sphygmomanometers and special patients such as the elderly and children.

There appears to be some evidence that the cuff sizes should be wider for children than has been recommended by the American Heart Association. In addition, it would be very useful to have a greater variety of cuff sizes available for young people. It would also be helpful to have a more reliable method for diastolic pressure detection in younger people.

It was pointed out that in the older population, problems exist that can confound blood pressure readings more than with other groups. Atrial fibrillation is one example of such a problem. With older patients, then, averaging a number of readings may be more important than a given reading. In certain situations (e.g., aortic valve disease), the fourth phase may be more useful than the fifth phase for diastolic indications.

Recent data from Canada report the inaccuracy of the blood pressure measurements that may be caused by stiff wall arteries. Errors on the high side of up to 50mm Hg have been shown in some older patients. Verification of these findings could have a significant impact on treatment for patients with stiff wall arteries.

On the question of testing, development of a test arm drew support. Looking to the future, use of a family of test devices to check sphygmomanometers could prove quite helpful. This is an area in which government or independent investigators could lend support.

A requirement for periodic testing of coin-operated blood pressure measuring devices should be inserted in any set of guidelines.

At the final plenary session, recommendations from each of the workshops were considered and were endorsed without change.

The conference was sponsored by the American College of Cardiology, American Heart Association, American Medical Association, Association for the Advancement of Medical Instrumentation (AAMI), Food and Drug Administration, the National Bureau of Standards, and the National Heart, Lung, and Blood Institute.

Workshop leaders were Alan S. Berson, Ph.D., National Institutes of Health (two workshops); William A. Baum, Jr., AAMI; Stephen S. Richman, AAMI; V. R. McCall, AAMI; William N. Reining, AAMI; and Maynard Ramsey III, M.D., Ph.D., AAMI.

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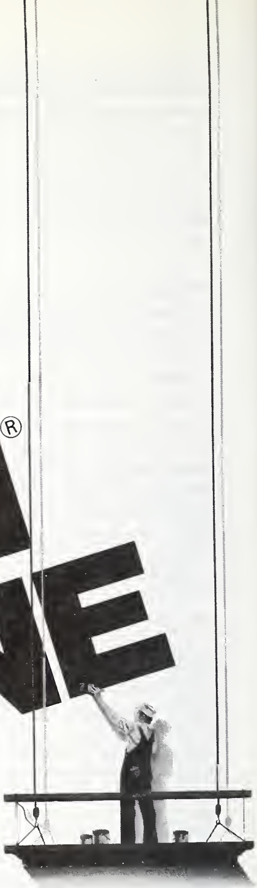

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ALAN J. WABREK, M.D., F.A.C.O.G., CAROLYN J. WABREK, M.ED.,
AND R. CLAY BURCHELL, M.D., F.A.C.O.G.

ABSTRACT—Grief is commonly experienced by the divorced woman. It can be dissected into three component parts—the need for love, affection, and sexual involvement. By separating the needs and understanding the relative importance of each, a woman can be helped.

The relationship between stress, change and illness is discussed and the importance of preventing unnecessary change is emphasized.

Divorce Counseling—Helping the Woman Cope

A marital relationship is bonded by a number of factors—love, affection, friendship, sex, children, home, career, being needed by someone else, and struggling against the world. In each specific marriage some of these factors have contributed more, and some less than others, to the life of the relationship. It is logical that after divorce, more pain will be associated from the—now missing—valued aspects than from others. Often people are unaware of the relative value of each aspect and they suffer pain without any perspective concerning the cause. The purpose of this paper is to clarify and simplify some of the counseling process that we have found to be most helpful in helping a woman cope with the termination of a marriage and the re-establishment of some of her need fulfillment.

Concepts

I. **Grief—**It is very helpful to start with an emotion such as sadness or grief, and identify the multiple causes. Most commonly the feeling is described as one of being "alone," and is caused by the loss of a partner, who, at least in part, had been very significant. When these feelings are analyzed and "teased apart," three components are usually present: the need for love, the need for affection or friendship, and the need for sexual involvement. The relative strength and importance of each need varies, and separating the needs can be extremely helpful because it allows the woman to see that these three needs are not equal, and what the particular hierarchy is for her. This discussion will further help the woman understand that in her previous relationship maybe one or more of these needs had not been met for a long time before.

In essence, a very large goal—sometimes almost hopelessly large—has been subdivided into several smaller manageable goals which will reduce stress.

II. **Relationships—**Dyadic friendships and relationships with others will change as a result of the divorce. When two individuals marry they form new friends, usually other couples. These new friends and relationships are not simply an amalgamation of the old friends that each knew as a single person. Likewise, when a marriage ends in divorce, these relationships will change. We personally have known of few individuals, or couples, that could remain equally friendly with both members of a divorced couple. It is an interesting phenomenon how difficult it is for a married couple to have, over the long term, a divorced woman or man as a close friend. As a consequence, old friendships are disrupted and new relationships will need to be formed. This transitional period can cause a woman to feel insecure because even though she was experiencing a lot of difficulty in her previous marriage, at least there was security in the old relationships.

III. **Sexuality—**A divorcee may be confused about

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her own sexuality. During the marriage, the woman may not have received any sexual advances from men. Her assumption may have been that this was because she was not desirable, and not very appealing. It is more probable that she was perceived as "unavailable" since she was married. The behavioral significance of this is that if a woman feels "unattractive" and a sexual advance is made, she will probably conclude that it was because she was provocative, and this may not integrate well into her self-concept.

Denial of sexuality presents other problems. If sexual feelings suddenly become acknowledged after a period of denial, the woman may be totally unprepared and vulnerable. No thought may have been given to contraception, venereal disease, or choice of partner. When dating, and the possibility of sexual involvement is very realistic, there is still a considerable adjustment. Marriage, no matter how bad, has provided some structure and security in the sense of knowing what to expect.

A major transition from marriage to dating involves forming new relationships with unknown expectations. A "date" may be aggressive or passive, attractive or not attractive enough, or too old or too young, and many individuals find it difficult to cope with these unknown factors. If the marriage has been of long standing, the change in sexual mores may present another problem, exemplified by the following case report:

The ten-year marriage of one of our patients ended in divorce. The woman had been a virgin when married; and although very responsive in her marriage, did not want to become sexually involved on a casual basis. She came for counseling because of her inability to find a solution to the "problem" of sexual involvement on a dating basis. Virtually all men she wanted to go out with let it be known that they did not want to date if intercourse was out of the question until they had known each other for a long time. They did not demand that she go to bed on the first date, but did not wish to become involved if her beliefs were such that sexual involvement was not a possibility for a long time. This was perplexing and confusing to her because in her past experience, intercourse was reserved for either the late engagement, or marriage.

During the ten years of her marriage the sexual mores in this country have undergone a tremendous shift for which she was not prepared. Any individual may be uncomfortable with changes in social ethics, but the divorced woman may suddenly find that she is bearing the full brunt of this change.

Treatment

One of the first questions to be asked may be: Why did it happen to me? If the woman did not want the marriage to end, she may continually agonize over why it happened. Questions such as—Where did she make a mistake? Could she have tried harder? What could she have done to prevent the divorce? These may be very difficult for her to answer without counseling.

Anger is common either as an effect or as a cause of the divorce. For many women, a marriage that has "failed" produces a considerable amount of hurt and pain which may result in anger towards her partner. Other women have experienced a considerable amount of anger during the marriage and may know that the anger was a cause of the marital difficulty and subsequent divorce. It is crucial in counseling the divorced woman that this anger be processed and dissipated if the woman is to move towards future relationships without a severe burden.

When a divorced woman comes in for counseling, we have found it most helpful to say something such as: "Individuals in your situation seem to have a number of problems. We have mentioned some of the ones that are fairly common. Have any of these concerned you or are there others that have not been mentioned? We can't discuss them all today, but take the one that you would like to start with and talk about it." This approach is low key, and appears to be very comforting. It oftentimes demonstrates to the woman that others, in like circumstances have similar problems and allows her a measure of control in her choosing the first topic to consider. This is "active" counseling. By knowing what some of the common problems are, the counselor can bring them up, suggest possible ways of reacting, and explore options for the future. This is less complex than classic psychotherapy in which the source of the feeling is more hidden and specific for each patient; and thus more time consuming and more difficult to understand. Most often the problem of loneliness is the first one to be discussed. It is important to clarify with the woman that loneliness may be subdivided into the need for love, affection and sex; and help her establish her own hierarchy of those needs. She is then asked if she would consider trying to satisfy each of these needs with different people rather than just one person. This question—suggestion—is usually surprising and the woman may ask if we are suggesting that she get sexually involved without either love or friendship. For the time being, we ask her not to consider the sexual component, but look at the love and affection parts. Would she consider separating the two and have these needs met with different people rather than just one person? If the woman reviews her close relationships since the termination of the marriage, it will usually become quite apparent that there has been considerable variation in individual need fulfillment in these different dyads. The woman may not have really conceptualized that this was what was happening, but a careful review of past relationships will usually demonstrate it. This method is especially helpful for the woman who has gone through a traumatic divorce where relating to others may be difficult or impossible for some time because of either hurt or anger. Separating out needs requires less risk in each relationship than trying to integrate the three with one person.

Virtually everyone has acquaintances who could satisfy the need for friendship. If love and sexual involvement are excluded, the members of either sex could satisfy this need. Love may also be received and given by someone who is not necessarily a friend or sexual partner. The love of a child, family member, or very old friend, may be truly wonderful, especially when one is grieving. If we believed that love and sex had to be associated, love from these sources would either not be acceptable, or would not be considered to be so satisfying. Whether or not to become sexually involved is the woman's decision. As counselors, we would say that at the present time, it is one of the options condoned by our society and should be considered and discussed. Sexual involvement without love, and possibly without friendship will offend some, but prove rewarding for others

The concept of separating and identifying component parts can also be extended to other aspects of the past marital relationship. It can be helpful in reducing suffering. The following case history exemplifies this point:

> A woman was very upset after a divorce. In retrospect, she realized that the divorce had been inevitable and that she had not loved her husband for some time. Her life was much less hectic without him. She was financially secure and the children were grown, and she could not imagine why she was suffering so much since the divorce. With counseling she became aware that she had not thought divorce was proper, had denied the loss of love and in fact had really "invested" in the non-emotional aspects of her marriage, particularly towards the end of the relationship. She had taken a greater interest in her home, had significantly helped her husband to succeed in business and had gone out of her way to enhance his rather shaky relationship with their children. What upset her so much was that she had been "so stupid" as to heavily "invest" in a marriage that was falling apart. This discovery made it possible for her to process these feelings and realize her actions were logical for one in her position.

Stress and Change

Change in a person's life frequently acts as a stress. Some stresses can be dealt with satisfactorily; others produce too much "strain" because the individual's adaptive capabilities are not equal to the task of handling them easily.

Rene Dubos,[1] who spent most of his life studying the habits and behavior of the tubercle bacillus, once said: "The more I study the tubercle bacillus, the less I think it has to do with tuberculosis." He did not mean the organism was unimportant but rather it is not the sole cause—the sole determinant of whether or not a person gets tuberculosis.

Graham and Stevenson,[2] have stated that: "While social stress is not the only factor significant in the occurrence of illness, it is our contention that it is highly relevant to most illness and that interpersonal stress is particularly so."

Other authors have reported on the relationship between stress, psychology and emotional factors in illness.[3-10]

Holmes and Rahe[11] devised a social readjustment rating scale by assigning a specific number of "life change units" to common transitions people make. They found that there was an increase in severe physical illness associated with more than 200 life change units during a twelve month period.[12] On that scale divorce was assigned 73 units. Other possibly inevitable changes after ending a marriage such as change in financial status or work were allotted 38 and 36 units. Changes in living conditions, residence, church and social activities were assigned 25, 20, 19 and 18 units respectively.

It is natural for individuals to respond to the stress of divorce by attempting to put their life back together again. Unfortunately, this may require additional changes which will add to the life change units. In many cases, it is better to adjust in a manner that requires the least amount of life change units, even though it may appear that life is disrupted for a time. An example will help clarify this:

Event	*Life Change Units*
Divorce	73
Change in financial status	38
Change in work	36
Change in social activities	18
	165

It may seem logical to move into a smaller house or apartment. That would add 20 additional life change units for a total of 185. Since the change is producing stress and severe physical illness is associated with more than 200 life change units, it is helpful that the woman understand the relationship between change, stress and illness. If financially able, it is wiser to postpone the move as the old house provides security even though there are painful memories.

As Grey Walter[13] has put it: "Facts accumulate at a far higher rate than does the understanding of them." The postponement of unnecessary change makes use of the facts and good common sense.

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Hospitals and New Enterprises

According to an article in the *Chicago Tribune,* hospitals, caught in a squeeze between overbuilding in the past and rising health care costs in the present, are seeking new enterprises "to generate income and to justify their existence."

The simple provision of "traditional acute care to the ill is no longer enough" for hospitals and "indeed, providing new services to people who are not sick is one of the fastest growing trends" among hospitals across the nation.

One example cited in the article is the health and fitness testing center at Chicago's Henrotin Hospital, where healthy people "are invited to get a basic physical examination and evaluations of their lifestyle, diet, overall strength and fitness," with a prescription for specific exercise and diet regimens.

A survey by the Chicago Hospital Council found that the most popular new programs offered by hospitals are clinics to help people stop smoking, lose weight and learn cardiopulmonary resuscitation. Health fairs also are "becoming a common annual event at hospitals eager to reach out into their communities." But not all hospitals "are turning to promoting health or preventive medicine as they adopt new programs," according to the article.

The Illinois Masonic Medical Center recently purchased a 325-bed nursing home. Gerald Mungerson, the Center's Executive Director, said that getting into nursing homes was a "natural" for the hospital because it is an area where service often is inadequate and because the population is getting older.

He said, however, that hospitals of the future will be "under governmental and economic pressure to economize." With government, insurance companies, and employers discouraging long hospital stays, hospitals must "protect their revenue base. We must find alternative sources of revenue to deal with this squeeze."

Elderly Health Screening Program

AMA BOARD OF TRUSTEES

At the December 1978 Meeting, the House of Delegates adopted a resolution by Connecticut calling for the Board of Trustees to study and review the Elderly Health Screening Program with particular emphasis on the cost/benefit effects, the relationship between the elderly and their own primary physician, and the legal obligation of physicians to whom screening reports are sent. The Board of Trustees asked the Council on Medical Service to review the subject, and the following report is based in part upon that Council's comments.

The Elderly Health Screening Program is financed by the federal Administration on Aging and state agencies on aging responsible for administration of plans under the Older Americans Act of 1965. The program is conducted through local health fairs designed to mobilize community resources to increase awareness of the health needs and problems of older people as a group; it utilizes preventive health education and screening procedures provided by community voluntary health organizations and state or area agency personnel. The programs utilize volunteer personnel and offer without charge testing for blood pressure, anemia, height and weight, and visual acuity, and counselling and referral for any potential abnormalities identified. Additionally, tests for hearing and screening for oral, breast, cervical and rectal cancer, glaucoma, tuberculosis and foot problems are made available where local resources permit. A panel of blood screening tests is offered at a minimal charge or with fees waived when funds are available and the need arises.

The site selection and arrangements for the screening program are arranged by the state or area agency on aging with participation of voluntary health agencies in the community. Medical and non-medical volunteers are recruited by the state and area agencies on aging with the cooperation of voluntary health organizations.

The federal Administration on Aging estimates the direct cost for a community health fair day that would screen 1,000 older persons to be $750. This includes mailing costs for follow-up reports and the costs of providing lunch for volunteer workers, but not any costs which may be incurred for laboratory procedures or personnel. (The laboratory tests are provided at a cost of $5 to $7 by a laboratory meeting standards and certified by the Center for Disease Control and Medicare.) The federal agency, in 1979, is furnishing $425 and the state and area agencies are asked to provide the remaining $325. The 1979 plans called for the screening program and health fair to be held in 610 sites in May 1979.

Experience with the screening and health fair program in 1978 indicated that 50% of all older citizens who had the complete battery of tests performed had one or more abnormalities calling for changes in health habits or prompt medical intervention to avoid potential problems. The Screening Program does not provide needed medical intervention or follow-up services. Participants who receive the screening tests receive copies of the results with an explanation that the results are *not* a diagnosis, only an indication that they should see a physician of their choice if the results are not within the normal range. The participant's physician, if one is named, is also sent a copy of the test results that includes the site of the health fair from which they originated. Telephone follow-up is provided by the health fair volunteer nursing staff approximately one month after the participants are screened, to make certain that participants understand any abnormalities detected during the screening program, and that they receive appropriate referral for further medical evaluation if they do not have a regular physician. Referrals when a participant does not have a regular physician are made through community resources.

In its study of Resolution 35, the Board also reviewed the Council on Medical Service Report on "Multiphasic Health Testing," which was adopted by the House of Delegates at the 1971 Clinical Convention, and the Council on Scientific Affairs Report on "Status of Multiphasic Health Evaluation," filed by the House at the 1978 Interim Session. The 1971 Council on Medical Service report notes that multiphasic health testing also can serve as one of the entry points into the health care system and should not be viewed as replacing or interfering with the patient-physician relationship. The report points out that such programs can be used to enhance the patient-physician relationship through the acquisition and interpretation of a broad base of health information on an individual.

Based on its study, the Board of Trustees believes that the Elderly Health Screening Program is conducted in a manner which will not adversely affect physician-patient relationships. The program places on the participant the responsibility to contact his or her own physician if the test results are not within an indicated normal range. Copies of the test results are also mailed to any physician designated by a participant, but the physician may return the test results to the testing laboratory, if he so desires.

With respect to cost/benefit effects, the 1978 Report of the Council on Scientific Affairs provided a com-

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EDITOR'S NOTE: This is a report of the AMA Board of Trustees adopted as amended herein by the House of Delegates at its meeting in December 1979. (Amendment in bold face).

prehensive review of experience with a number of multiphasic health testing programs. This report noted that:

> "Multiphasic health evaluations using paramedical staff under minimal medical supervision and with new technology provides screening at lower per-patient cost than alternative methods requiring substantial amounts of physician time. By separating the well from the sick patients, it becomes possible to develop programs of comprehensive health maintenance for the well, emphasizing improved health status through changes in life style and environmental conditions, and to initiate appropriate definitive medical care for those who need it. Multiphasic screening has not been very successful when follow-up on positive findings is lacking. It appears to require an organized setting such as occupational health programs, governmental and/or private agencies, insurance examination programs, and prepaid health care delivery systems to insure a continuum of health maintenance delivery at primary, secondary and tertiary levels of care."

The report concludes:

> "At this time, it cannot be decided whether the multiphasic approach will be cost effective in relation to the derived benefits. It requires many years of continuous operation of a properly designed study, with controls and adequate follow-up, to determine whether life style has been modified successfully and improved health has resulted. Currently, there is no study that meets these criteria. However, studies designed like the Kaiser-Permanente experiment, which is in progress, have the potential of providing answers to these pressing questions. Should health maintenance organizations fulfill their charters by emphasizing prevention through screening and health maintenance, they could add valuable information. Whether it is possible to improve the health of groups on a sustained basis, at a cost resulting in savings to the overall health and medical care system, by using the tool of multiphasic screening remains to be demonstrated."

With regard to the obligations of physicians to whom elderly health screening reports are sent, the following legal considerations are noted:

> The physician who receives unsolicited reports on laboratory or other diagnostic procedures performed in conjunction with the Elderly Health Screening Program may elect to accept as a patient any participant who designated the individual physician to receive the report. If the physician elects not to accept such persons as patients, the Board recognizes that returning the report may impose an additional administrative burden on the physician's practice. However, it is advisable that the report be returned to the Elderly Health Screening Program so that it can inform the participant of the need to make arrangements to see a physician for any needed evaluation of the report or follow-up care.*
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> The Board also recognizes that receiving these reports from the Elderly Health Screening Program on patients whom the physician is seeing currently or has seen from time to time may create an additional burden on the physician's practice; but it is advisable that the physician communicate with the patient if treatment or further testing appears needed, based upon the results of the screening.*
>
> Failure either to return the form or to communicate with the patient may result in the physician's exposure to legal ability should the results indicate a need for prompt medical attention.*

Elderly Health Screening Programs should be encouraged to continue to provide telephone follow-up to make certain that participants are aware of any abnormalities detected during the screening program and make arrangements for appropriate referrals to their regular physicians or through community resources for further medical evaluation.

The Board of Trustees also believes that the responsibility of the person screened to seek further medical evaluation from a physician of any abnormal screening test results should be stressed to all who undergo such testing. The Board therefore recommends that it be the policy of the Association to encourage the inclusion of a statement to that effect in the educational material provided any person participating in a multiphasic health testing program, including those conducted by the federal Administration on Aging and state agencies on aging. Such a statement should emphasize that screening test results are not a diagnosis and do not obviate a need for periodic health examinations by a physician, **and that it is the responsibility of the administrator of the health test plan to notify the patient who has been screened to seek follow-up medical evaluation for all abnormal test results.**

The Board has requested the Council on Medical Service to continue its review and monitoring of multiphasic health testing activities, and to report further to the Board and the House at any time that a reevaluation of present Association policy on this subject is indicated.

The Board of Trustees believes that this report and the above cited reports of the Council on Medical Service and the Council on Scientific Affairs respond to the concerns expressed in the Resolution, and recommends adoption of this report.

EDITOR'S NOTE: *These three paragraphs marked with asterisks were not adopted with the rest of the report by the AMA House of Delegates but were referred back to the AMA Board of Trustees for further study (and report back to the House for its July 1980 meeting).*

The response of the Council to this program is on p. 329.

Status of Multiphasic Health Evaluation

AMA COUNCIL ON SCIENTIFIC AFFAIRS

This report reviews the scientific literature for the past three years to evaluate what progress has been made in determining the effectiveness of health screening procedures. It is important to compare the health maintenance and early disease detection accomplishments with the costs of the programs.

The Kaiser-Permanente prepaid health care plan experiment, which began in 1970, was based on the concept of triage through multiphasic screening conducted by paramedical staff to separate the well and worried well from the asymptomatic and symptomatic sick.[1] The latter are referred to a staff physician for definitive medical care. The well and worried well are exposed to various modalties of health education and counseling. An important key to success of this program is the regular follow-up of those patients who have deviations from what is considered to be normal good health, such as mild obesity, slight elevation of blood pressure, or poor health habits. The Kaiser-Permanente data show that 68.4 percent are identified as the well and worried well, with 31.6 percent composing the asymptomatic and symptomatic sick groups. In the well and asymptomatic sick groups the savings for entry work-up varied from 0.52 physician hours and $29.03 per patient in the former to 0.59 hours and $34.98 per patient in the latter. There was also a considerable savings in the sick group for entry work-up: 0.43 physician hours and $24.79 per patient. For all four groups there was a savings of 0.50 physician-hours and $28.21 of physician costs per patient in the entry work-up process, an average savings of about 70 percent in the physician time and costs as compared with the traditional system. This new approach entirely avoided the previously required initial physician appointments. Only 8.9 percent of patients were referred for follow-up staff physician care; an additional 17.2 percent were referred to physicians in other specialties. Surveys have demonstrated both patient and staff acceptance of and satisfaction with the new system in the 90th percentile.

In 1972, the University of Utah, College of Medicine, instituted a 15 months' study designed to determine the impact of Automated Multiphasic Health Testing on morbidity and attitudes involving 574 families of various social and economic strata.[3 5] These families were selected randomly: one-third were from a neighborhood health center representing a low income group enrolled in a prepaid health care program; one-third were nearest neighbors to families in the first group and were not members of the neighborhood health center; and one-third were employees and families of a local utility company chosen to represent a population of middle income workers. No organized attempt was made to accomplish education, counseling or follow-up of the participants. Investigators concluded the critical determinant for acceptance and utilization of multiphasic screening lies beyond the screening process itself. The identification of abnormalities has little value without physician interpretation and intervention. Commitment from the medical community is essential before screening can be expected to affect the patient who uses it.

Sweden, with a more homogeneous population than America, provides free and voluntary multiphasic screening for all 4-year-old children.[4] Health problems of functional importance were found in 21.6 percent of the 155,000 children screened during 1971. Of these problems, 71.8 percent were newly discovered by the screening. Excluding referrals for dental care, the prevalence of health problems was 15 percent, and 57.6 of these newly found conditions. Other health defects frequently identified were visual, neurological, auditory and surgical in nature.

In 1974, a study at the University of Texas Health Service Center, based on national statistics, demonstrated substantial savings would result over a twenty year period, if a program of "Early and Periodic Screening, Diagnosis, and Treatment" was introduced nationally.[4] The five fields were: mortality of infants to

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EDITOR'S NOTE: This is a report of the AMA Council on Scientific Affairs to the House of Delegates at its meeting in December, 1979.

age 1 year; mortality of young persons from ages 1-21 years; rehabilitation costs for chronic diseases; costs of physician visits; and hospitalization costs. It was concluded on a nationwide basis the gross dollar savings over a twenty year period would be $30 billion in reduced infant mortality; for persons 1-21 years, $7.4 billion; for rehabilitation of children and youths under 18 years of age with chronic diseases, $432 million; for reduced morbidity resulting in fewer physician visits, $459 million; and for reduced hospitalizations, $1.6 billion. There would be a cumulative dollar savings of $34.5 billion or $43 billion in 1976 currency after substracting the costs for the program of $5.4 billion.

The Michigan Department of Public Health Plan for Early and Periodic Screening, Diagnosis, and Treatment began in 1973.[4] By October 1976, 425,000 persons had been screened, representing 10 percent of all Medicaid screenings in the United States. Persons under 21 years are offered screening initially when they become eligible for Medicaid. The recommended intervals for subsequent screenings are: infants under 1 year, every six months; and persons 1 through 20, every three years. The screening tests are multiphasic and include an unusually thorough battery of tests and evaluations. The average cost per screening in 1975 was $30.21. The data thus far indicate the necessary referrals for health care are becoming less frequent. While more time is needed before firm conclusions can be drawn, those responsible for the plan believe it is financially and medically sound to correct conditions which would otherwise result in serious health impairments for many of the young people.

At the university of Lund, Malmo, Sweden, a prospective study began in 1969 to determine the effects of health screening on mortality and causes of death in middle-aged men.[6] All men born during even numbered months in 1914 and living in Malmo were invited to participate in an investigation regarding risk factors for cardiovascular disease. Individuals with a blood pressure of 165/110 and over were treated, and a sub-sample of heavy smokers was later invited to take part in a smoking-cessation project. During the following five years, total and cause-specific mortality in the examined group were compared with corresponding data for men born during even months in 1914. Mortality in the examined cohort was lower than among the controls and differed significantly with regard to cardiovascular disease.

During 1977, many scientific papers were published reporting favorably on the value of early identification and appropriate intervention through screening procedures to identify single risk factors. Some of the most rewarding experiences were in the early detection of asymptomatic hypertension, cervical cancer and breast cancer. However, equally encouraging results were reported in screening for scoliosis; urinary infections in females; and heart abnormalities in school children. Many of these reports not only indicated a yield of positive findings, but also gave information regarding cost effectiveness.

The Multiple Risk Factor Intervention Trial is an excellent example of a large prospective study designed to determine whether preventive intervention techniques applied to high-risk subjects with multiple risk factors can effectively influence health status.[7] The National Health and Lung Institute proposed a six year primary prevention clinical trial involving 12,000 male participants between the ages of 35 and 57 years, who, through screening procedures, were considered to be at high risk for the development of coronary heart disease because they possessed three high-risk factors, namely, elevated blood lipid levels, hypertension, and cigarette smoking. The trial began in 1972 with eight clinical centers participating, and twelve more centers followed during the next eighteen months. Participants were divided equally into an "intervention" cohort and a "usual care" cohort. The "intervention" cohort is being managed through group and individual health education, counseling, and appropriate drug intervention. The "usual care" cohort is being allowed to follow their own dictates and those of their personal physicians. The primary end point of this study is death ascribed to coronary heart disease. It is still too early to know how successful this type of intervention will prove to be.

Dr. James Banta and Dr. Robert Franklin of Tulane University School of Public Health succinctly stated the ingredients of a successful multiphasic screening program.[2] They wrote:

> "It must be remembered that the essential factor of a successful outcome from screening is education. Patient education is not only the key to early detection (whether this detection comes about by simple awareness, self-examination or screening), but it also initiates a process which leads to appropriate intervention. Appropriate intervention is fundamentally and finally determined by change in health behavior. While a change in health behavior is an individual and personal matter, the physician cannot escape the responsibility for vigorous counseling, a thorough patient education program, and a search for methods to truly change health behavior. Obesity, cigarette smoking, excessive alcohol use, and imprudent diets are unlikely to ever yield to surgical or pharmacological intervention, but health behavior can be changed."

Multiphasic health evaluations using paramedical staff under minimal medical supervision and with new technology provides screening at lower per-patient cost than alternative methods requiring substantial amounts of physician time. By separating the well from the sick patients, it becomes possible to develop programs of comprehensive health maintenance for the well, emphasizing improved health status through changes in life style and environmental conditions, and to initiate appropriate definitive medical care for those who need it. Multiphasic screening has not been very successful when follow-up on positive findings is lacking. It appears to require an organized setting such as occupational health programs, governmental and/or private agencies, insurance examination programs, and prepaid health care delivery systems to insure a continuum of health maintenance delivery at primary, secondary and tertiary levels of care.

At this time, it cannot be decided whether the multiphasic approach will be cost effective in relation to the derived benefits. It requires many years of continuous operation of a properly designed study, with controls and adequate follow-up, to determine whether life style has been modified successfully and improved health has resulted. Currently there is no study that meets these criteria. However, studies designed like the Kaiser-Permanente experiment, which is in progress, have the potential of providing answers to these pressing questions. Should health maintenance organizations fulfill their charters by emphasizing prevention through screening and health maintenance, they could add valuable information. Whether it is possible to improve the health of groups on a sustained basis, at a cost resulting in savings to the overall health and medical care system by using the tool of multiphasic screening remains to be demonstrated.

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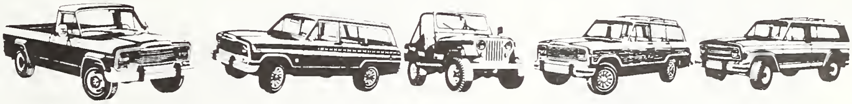

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The AAMC and Medical Education in the 1970's

JOHN A. D. COOPER, M.D.

The last two decades have been a turbulent period in the history of our country. The quiet Eisenhower years gave way to an era of assassination, violent civil rights protests, student revolts, a debilitating war in Vietnam, scandals in the Executive and Congressional branches of the federal government, accelerating urbanization that brought serious problems including decay of inner cities, an energy crisis, double-digit inflation, and a severely weakened dollar. However, until recently, real individual incomes have risen; people are doing better and, despite what John Knowles said, not all are feeling worse.

In the midst of this turmoil, medicine and medical education have changed, mostly for the better. The new knowledge flowing from an expanded research effort transformed medical practice and moved it a considerable way from empiricism to a more solid scientific basis with a corresponding greater capability in the prevention, diagnosis, and amelioration of disease. Life expectancy has been extended, and significant reductions in morbidity have been achieved. As a result, the American people have raised their expectations of medicine, and this has brought greater demand for medical care. With increasing demands have come more public anxiety and concern about the cost, quality, and accessibility of these services. This outcome was predicted by Jerome Bruner in 1962: "With technological advance, more things are possible, but social and technical organization is increasingly necessary to bring them off. In effect then, the sense of potency—the idea of the possible—increases in scope, but the artificer of the possible is now society rather than the individual." As Bruner foretold, we have suffered exponential intrusion of government into medicine and medical education and through mounting directive legislation and regulation. This intrusion has resulted in a severe restriction on the past freedoms and capabilities of medical schools to innovate.

The medical schools have grown in size, complexity and function. The number of schools has increased from 99 in 1969 to 126 today. The number of undergraduate students has risen from 35,000 to 62,000. This 75 percent growth in ten years equals that of all three previous decades. Not only have the medical schools increased the number of graduates, but they have also assumed a broader role in the continuum of medical education. Now more than 90 percent of the residency programs are in teaching hospitals associated with medical schools. This contrasts with less than 50 percent 15 years ago. This greater involvement brings increased responsibility for the medical schools to assure the quality of residency training and to relate it to the nation's needs for physicians. Continuing medical education has grown enormously in the last decade as one effort to improve the quality of medical care provided by practicing physicians. Medical school faculties have become major participants in continuing medical education through programs offered by the medical schools or through professional societies and associations. A host of other learners in the academic medical center have put additional burdens on medical school faculties. In 1960, the faculties were involved in teaching a total of 89,000 students of all types, by 1976, the number had increased to about 155,000.

Faculty involvement in biomedical research has not grown concomitantly, in spite of the seminal contributions that new knowledge has made to the advancement of medicine. Although appropriations for the National Institutes of Health, the major source of support for biomedical investigations, have risen from \$1.1 billion in FY 1969 to \$3.2 billion in FY 1979, this additional funding does not represent any real increase in research effort because of inflation and higher costs of more sophisticated investigations. Fragmentation of funding by "disease of the month" campaigns and detailed directives in federal legislation have significantly re-

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JOHN A.D. COOPER, M.D., President, Association of American Medical Colleges. This article is adapted from a presentation given by Dr. Cooper at the 90th Annual Meeting of the Association of American Medical Colleges, Washington Hilton Hotel, November 6, 1979, on the occasion of his tenth anniversary as AAMC President.

duced the flexibility to pursue the most promising directions in research.

During this period, the Administration, and particularly the Office of Management and Budget, heightened their opposition to federal involvement in research training. As a result, more restrictions have been placed on support for preparing the next generation of investigators. These constraints, along with the plateau in research grant funding, threaten the national research endeavor and the future supply of faculty for the medical schools.

The situation is quite different with regard to medical services provided by the academic medical centers. To assure the transfer of new knowledge from the research laboratories into medical practice and to meet society's demands for complex, tertiary care, the full-time clinical faculties expanded from 15,916 in 1969 to 22,059 in 1979 and became more involved in medical care. Over 20 percent of acute inpatient hospital days are now provided by the 323 non-federal members of the Associaton's Council of Teaching Hospitals that constitute only 5.4 percent of the nation's hospitals. In addition, Veterans Administration hospitals affiliated with medical schools and belonging to the Council provide over two-thirds of VA inpatient hospital days, though they make up only about half of the hospitals in that system.

Medical schools have also extended their activities beyond the walls of the academic medical center through affiliations with many community hospitals and VA hospitals and through the creation of area health education centers with other institutions involved in health professional education and patient service. These developments have contributed to the dissemination of new knowledge and technology, the improvement of the quality of medical care, and better geographical distribution of physicians.

The growth and changes in academic medical centers over the past decade have been reflected in the financing of their activities. The total budgets of the medical schools have more than trebled. In 1969, over one-half of medical school budgets came from federal grants and contracts. Now less than one-third comes from this source. Increased state government support has been of critical importance to both public and private medical schools, and professional fee income from medical practice by the clinical faculty has become more important as other sources or revenue have lagged behind the medical schools' needs. However, many private and some publicly controlled medical schools have been forced to increase tuition fees substantially in order to maintain their fiscal viability.

These changes in the sources of revenues threaten the balance in medical education, research, and patient care activities. The expanded involvement of the clinical faculties in medical service is diminishing the time they can devote to education and research. Moreover, increased tuition and inadequate sources of student financial assistance are making it difficult to sustain efforts to broaden the socioeconomic levels of medical school classes and to improve opportunities for underrepresented minorities.

The growth in size and function of the academic medical centers and the problems of obtaining adequate financial support for their activities have brought about important changes in the relationships of the medical school to its parent university. University officials and trustees have become more active in medical school affairs. The issues that have raised the university level of concern center primarily around medical service activities and university-owned teaching hospitals. Because of these concerns, many institutions have created the position of vice president for health affairs. Although the role of these vice presidents varies widely, in some cases they have been given broad responsibilities over the educational and patient care activities of the medical school and university-owned teaching hospitals. The new organizational pattern has weakened the ties of the medical school to the remainder of the university and has often created difficulties in defining the roles of deans and hospital administrators. The resulting instability comes at a time when cohesively, effectively operating academic medical centers are of rising importance.

The Association of American Medical Colleges has responded in several significant ways to the changing world in which the medical schools operate, and has assumed a greater leadership role in medicine and medical education to provide more effective support to academic medical centers. In the last decade the Association has been transformed from a "Dean's Club" into an organization broadly representative of all those involved in the increasingly complex structure of the medical schools and their affiliated institutions. In addition to a Council of Deans on which the dean of each U.S. medical school serves, the Association's membership and governance structure has been expanded to include the Council of Teaching Hospitals, the Council of Academic Societies, and the Organization of Student Representatives. The Council of Teaching Hospitals now has 418 members and represents the major institutions involved in undergraduate and graduate medical education, clinical research, and complex and highly intensive tertiary care. Membership in the Council of Academic Societies has doubled since 1969, and its 70 professorial and specialty societies represent more than 100,000 individuals. The Organization of Student Representatives, formed in 1971 with participants from 112 medical schools, brings the student voice to the Association. All segments of the academic medical center now work effectively in concert to develop the policies and programs of the Association and make it an effective spokesman to policy-makers.

The Association has also become more involved with other groups in education and health to broaden its influence on national policy issues. It was instrumental in creating the Coalition for Health Funding, which brings together the efforts of 55 private sector organizations to improve the level of funding for federal health programs. The Association has also joined with four other major medical organizations to establish the Coordinating Council on Medical Education to develop broad policy and has been a major contributor to the development of the Liaison Committees on Graduate Medical Education and Continuing Medical Education. On a regular but less formal basis, Association representatives meet with officials of other scientific or educational organizations to discuss and act on issues of common importance.

To obtain the advice and counsel of a distinquished group of private citizens and to promote a better understanding of the Association's objectives and programs and of the needs of the academic medical centers, the Association established a National Citizens Advisory Committee for the Support of Medical Education. The Committee members are 53 prominent individuals from business, the arts, and civic affairs. Through its issue papers and contacts with policy-makers, the Committee has been important in making public the Association's messages.

In keeping with these litigious times, the Association has been increasingly involved in the courts, particularly the federal courts, either as a plaintiff or *amicus curiae* to try to overturn or moderate damaging legislation or regulation. The outstanding success in the legal arena was the forced release of $225 million in research funds impounded by the Nixon Administration. The Association has also participated actively in hearings held by federal agencies. The action of the National Labor Relations Board in defining residents as students, rather than employees, was an outcome of this kind of effort.

The total annual budget of the Association has more than trebled since 1969. At the same time, there have been notable changes in the sources of revenue. In FY 1969, 31 percent of the income was from membership dues; in FY 1979 only 20 percent came from this source, but this component of income has been, and continues to be, critical for Association programs. Income from grants, contracts, and services now accounts for three-fifths of the Association's revenue.

There have been a number of new programs undertaken over the past decade with the assistance of steering committees drawn from the constituency and with financial support largely from foundations and government agencies. One of the most effective of these programs has been the Management Advancement Program which is designed to improve the management capabilities of deans and their management teams, department chairmen, and teaching hospitals administrators. More than 800 individuals have participated in 40 seminars made possible by a generous grant from the Robert Wood Johnson Foundation. Among other activities and programs have been studies of the characteristics of medical schools; affiliation agreements; primary care education; the teaching of quality assurance and cost containment; health maintenance organizations; three-year medical school curricula; medical practice plans; the source, mobility, and career patterns of faculty; characteristics of medical school applicants and enrollees and their financial support; careers plans of medical students; noncognitive evaluation criteria for selecting students; and a major followup and analysis of the longitudinal study of medical students begun in 1956.

Among the services provided to the Association's constituents are the American Medical College Application Service, a centralized application service through which more than 30,000 students file 300,000 applications to 96 participating medical schools; the New Medical College Admission Test, which provides an intensive evaluation of knowledge applicants possess in the premedical sciences and their ability to solve problems similar to those confronted by a physician; the monthly *Journal of Medical Education* and a variety of other periodic publications; and an array of information systems on medical schools, faculty, teaching hospitals, applicants, and students.

The accomplishments of the Association in the last ten years have been due in large part to the leadership and contribution of hundreds of individuals who have served tirelessly on the Executive Council, the Administrative Boards, task forces, and committees. Although the last decade has been an exciting period of growth and accomplishment for the Association, we cannot become complacent.

The challenges of the next decade will be even more demanding. For example, we are moving to respond to an important recommendation of the Association's 1965 Coggeshall report: "Those responsible for medical education—faculty members, deans, university officials, trustees, and legislators— will, in decades ahead, need to devote careful attention to appraising the needs of society for health care and health personnel and to developing and implementing plans to meet those needs. Failure to do so will damage the standing of the profession and educational institutions and will incite—even make necessary—less desirable approaches to meeting the health care needs of a growing America. If those responsible for medical education fail to assume and act on a responsibility that is now clearly theirs, it will be assumed by others."

This and other opportunities to advance the nation's health remain urgent items for the Association's agenda.

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The FDA New Drug Approval Process

RAY W. GIFFORD, JR., M.D.

Mr. Chairman:

My name is Ray W. Gifford, Jr., M.D. I am head of the Department of Hypertension and Nephrology at the Cleveland Clinic in Cleveland, Ohio and am a member of the AMA Council on Scientific Affairs. I am also one of AMA's representatives to the National Council on Drugs and immediate past chairman of that Council. With me today are John C. Ballin, Ph. D., Director of AMA's Department on Drugs, and Ross Rubin, Assistant Director of our Legislative Department.

We are pleased to present the views of the American Medical Association concerning the issue of the so-called "drug lag" in this country and how it relates to the new drug approval process conducted by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug and Cosmetic Act.

Let me state initially that the AMA supports the concepts expressed in existing law designed to carry out the public policy that only safe and effective drugs be available for marketing in this country. This public policy has created a profound change in the development and marketing of pharmaceuticals since the implementation of the original Pure Food and Drug Act in 1906. Gone are the days of snake oil and medicine show treatments. No longer need the public be concerned about patently toxic products, such as the ill-fated elixir of sulfanilamide, or about nostrums being huckstered on the open marketplace. The medical profession has, from the beginning, supported efforts to protect the public health and cooperated with the Federal government in this long-standing endeavor.

Safety and efficacy of drugs and other medical treatments can never be absolute. There is always some risk of therapeutic failure or adverse reaction from the use of any drug. Furthermore, there are varying degrees of risk of adverse effects that can be tolerated for certain drugs because of the nature of the condition being treated or the availability of alternate treatment modalities. Likewise, different levels of efficacy are also acceptable depending upon circumstances. Rather than being an exact science, drug evaluation is, in reality, an art that is scientifically based. For this very reason, after FDA approval of a drug, the physician provides the final safeguard for the public by prescribing drugs for patients only after considering the individual needs of the patient being treated and the benefit risk ratio that applies to that particular patient from the use or non-use of the drug. It is in this context that we are addressing our comments about a problem that we have perceived concerning the regulation of drug research and approval in this country.

In recent years, physicians have noticed a disturbing trend that drugs ultimately approved in the U.S. as major treatment break-throughs—drugs that subsequently become the drugs of choice—have been available in other countries for significant periods of time prior to U.S. marketing. This trend is especially troubling when the drug provides a therapeutic breakthrough over other available treatment modalities. Even when the improvement in treatment is only incremental, failure to have such improvements available means there is a therapeutic detriment to patients through the limitation of the armamentarian available to physicians to treat illness and injury. This situation has been characterized as the "drug-lag."

While there has been extended debate as to the existence, scope and therapeutic impact of the "drug-lag," it is undisputed that certain drugs have been available overseas prior to the time of U.S. approval. These include drugs such as cimetiadine for peptic ulcer treatment and sodium valporate for use in the treatment of epilepsy. Attached to our statement is a more complete list of drugs now available in the U.S. that were marketed earlier in foreign countries. We consider these important drugs that could have made significant improvements in therapeutics had they have been available earlier in the United States.

Mr. Chairman, I would like to discuss how this "drug-lag" has impacted upon my practice. My own expertise is in the area of hypertension, with special emphasis on drug management of this condition.

Since 1963 most of the new anti-hypertension drugs have been marketed first outside the United States. Included in this group are clonidine, prazosin, diazoxide, and two loop diuretics, ethacrynic acid and furosemide and all of the beta blockers. In addition, such compounds as bethanidine, bumetanide, debrisoquine and amiloride are not yet available in this country even though they have all been marketed in Europe for more than 5 years and in the case of bethanidine since 1963!

RAY W. GIFFORD, JR., M.D., head of the Department of Hypertension and Nephrology, Cleveland Clinic, Cleveland, Ohio, and a member of the AMA Council on Scientific Affairs.

EDITOR'S NOTE: This is a Statement of the American Medical Association given before the Subcommittee on Science, Research and Technology Committee on Science and Technology, U.S. House of Representatives on June 21, 1979.

One of the most important advances in the treatment of hypertension in the last decade has been the use of beta blockers. In this country, the first beta blocker approved was propranolol, but it was not approved for treatment of hypertension until 1976, seven years after it was approved for this purpose in Great Britain. There are now seven beta blockers available in Europe (and some also in Canada) that are not on the market in the United States. Some of these have at least theoretic advantages over the two blockers that are on the market in this country. One of them has alpha (in addition to beta) blocking activity that appears to make it more potent.

Two of the most potent diuretics we now have, ethacrynic acid and furosemide, were marketed in Europe fully two years before American physicians had access to them. They are the only diuretics that are effective for patients with impairment of kidney function. Often these drugs made it possible to control hypertension in patients with kidney disease when the blood pressure had been resistant to other combinations of available drugs. British patients had the advantage of these two potent diuretics for two years before American patients did.

In 1963, I published the results of an investigation of a new drug, bethanidine. I confirmed the findings of European and Australian investigators that it was a potent and useful drug that had definite advantages over other drugs then available for a well defined group of severely hypertensive patients. Bethanidine was approved for marketing in the United Kingdom in 1963. Subsequently it has become available in every other country in the world (including Canada), except the United States! This has led to the situation where I can prescribe bethanidine for my Canadian patients and not for my American patients.

Fortunately hypertensive crisis is rare, but when it occurs the survival of the patient depends upon prompt reduction of blood pressure by giving potent drugs into the vein or muscle. There can be no argument that drugs that are effective in major hypertensive crisis are lifesaving with diazoxide being one of the most effective. It has only been available to American physicians for six years even though it had been under investigation for over 10 years before it was approved and had been marketed in the U.K. for almost a year and in Australia for 3 years before it was approved in the United States. The other potent drug used to combat hypertensive crisis is sodium nitroprusside. The first publications, including one of my own, describing its use for treating hypertensive crisis appeared more than 20 years ago but it was not accepted for marketing by FDA until 1974. In defense of the FDA, I must point out that this was not a case of "drug lag" as it has been defined. In fact, this was a rare example of an important new anti-hypertensive drug being marketed first in this country. However, there must be something wrong with our drug regulatory system when a drug that is recognized in our country by authorities in the field as unique and life-saving is not made available to the practicing physician for 20 years after the first description of its potential value.

The advances in the prevention and treatment of illness in recent decades can largely be attributed to the explosion of innovative drug products developed and produced in this country. Not only have treatments been found for conditions that could not be previously treated, but drug therapy is also often the safest and most cost effective treatment available. Continued progress in improving medical treatment in this country will be largely dependent upon the continued flow of new and improved drugs. Therefore, it is incumbent that basic and applied research in drug treatment be fostered.

While no one expects the same rate of new drug introduction that followed the major scientific breakthroughs after World War II, it is important to create a climate that encourages the development of new drugs. Available evidence indicates that private sector expenditures for drug research and development have kept pace with inflation and have, in fact, grown in real terms. However, this increased expenditure comes from a vastly reduced number of companies that do basic pharmaceutical research. *Today, out of 800 drug manufacturers only 25-30 maintain full large-scale research operations. Also, a greater percentage of research and development funds are being spent to meet regulatory requirements and not for innovative and creative work.* It is also a fact that more and more American drug companies are funding research overseas and introducing drugs in other countries prior to seeking approval in the U.S. Since new drugs are being developed and introduced in other countries, we can only conclude that this trend toward off-shore research and later introduction is attributable to the regulatory climate in this country.

No one can fault a reasonable evaluation of drugs for their safety and efficacy. No one wants to see another elixir of sulfanilamide or thalidomide tragedy. While less visible, however, there are many other tragedies when patients with very real illnesses cannot procure the most advanced and effective treatment possible. When overly stringent regulations and requirements, agency delay, and agency conservatism unduly retard drug approval, or worse discourage investigators from seeking new discoveries and marketing approval, then change is necessary. Drug research and development is an endeavor that can only be undertaken now by those with large financial resources and staying power. *From the time of discovery to the time of FDA market approval, a drug innovator can expect to spend 7-10 years and as much as $30,000,000. While Section 505 of the Food, Drug and Cosmetic Act expresses Congressional intent that the "new drug" applications be approved expeditiously (within 180 days of filing),* *in actuality the average approval time from the submission of an NDA is 2-3 years. More often than not FDA requests an extension of the deadline for action and the drug's sponsor feels compelled to agree to the extension or face adverse action on the application.* When data from non-U.S. conducted studies are used by an innovator, FDA has consistently required domestically conducted confirmatory studies regardless of the quality of the foreign work. *In comparing activities in the U.S. to those in the United Kingdom, it was found that in approving a drug, 25 times as much paperwork was required in the U.S. as compared to the U.K. and it took twice as long to process the applications here.* Also, increasingly detailed regulations of biomedical and drug research by FDA may be discouraging the best biomedical researchers from participating in "new drug" research.

While these regulatory activities by FDA have most likely reduced the risk that drugs introduced in the United States will be unsafe or ineffective, such activity should be measured against the therapeutic costs of such increased safety. This is especially relevant in this area where risk-free drugs are an impossibility. We do not believe that at this time the benefits derived from FDA's current safety and efficacy procedures and conservatism exceed the detriments that are caused by the lack of availability of new drugs in the U.S.

The AMA House of Delegates in June of 1974 noted its concern about the developing drug lag. The policy statement required AMA to begin efforts to effect a change in the Nation's drug law "so as to make safe and effective drugs readily available to the American people." In June of 1977, AMA again reviewed its policy concerning the drug approval process and, while supporting the continued governmental role in reviewing drugs for safety and efficacy, determined that AMA should develop amendments to the Food, Drug and Cosmetic Act designed to expedite the availability of safe and effective drug products. This led to the development of a series of amendments to the Act that were introduced in the 95th Congress by Representative Tim Lee Carter as H.R. 12485 (attached) Amendments in the package that are relevant to his Committee's inquiry would:

1. provide authority for the Secretary of HEW to allow the limited marketing of "break-through" drugs without the receipt of full efficacy data;
2. establish a procedure of an investigational new drug protocol agreement between FDA and a drug sponsor to determine FDA's research requirements for the drug at an early point in time;
3. provide fixed deadlines on certain actions of the FDA and establish limits on the extensions of such deadlines;
4. provide a drug sponsor the opportunity to resolve scientific disputes with the FDA before a select panel of the National Academy of Science;
5. provide specifically that well-controlled clinical investigations conducted overseas would be recognized on an equal basis with those conducted in the U.S.; and
6. provide authority to the Secretary to suspend a drug's approval or modify labeling for the drug after an expedited hearing if the drug poses a serious and substantial risk of harm to the public health.

Along with these amendments, the AMA has continually called for increased funding for the FDA so that its scientific capability could be upgraded so it would be able to attract the highest quality staff possible.

Mr. Chairman, no segment of society recognizes and appreciates the benefits to health that can be attributed to the activity of both the American pharmaceutical industry and FDA more than does the medical profession. However, we cannot support agency action that unduly delays the introduction of innovative drug products in this nation. We cannot condone a regulatory climate in this country that is inhibitory to research and development of innovative drug products. Such a situation does not benefit our patients. Changes are needed. It is important for all parties involved in the process to recognize a mutual interest in providing safe and effective drugs for the American public. The American Medical Association stands ready to work with this committee as it seeks to identify needed reforms to existing law and regulations designed to expedite the drug approval process and improve the climate for drug research in this country without sacrificing public health or safety.

Listed below are a number of drugs that, for the most part, are available now in the United States but that were marketed much earlier in foreign countries. These are important drugs that could have made significant improvements in therapeutics if they had been available earlier in the United States. This list is not meant to be inclusive since other drugs fall into this category.

bretylium tosylate	adrenergic blocker
levodopa	anti-Parkinson
baclofen	muscle relaxant
sodium valproate	antiepileptic
butorphanol	analgesic
carbamazepine	treatment of trigeminal neuralgia
cimetiadine	antiulcer
disopyramide	antiarrhythmic
diazoxide	antihypertensive
prazosin	hypertension
beclomethasone	antiasthma
cromolyn sodium	antiasthma
danazol	gonadotropin
bromocriptine	prolactin inhibitor (also for Parkinsonism)
desmopressin	antidiuretic
calcitonin	blood calcium regulator
dinoprost	protoglandin
rifampin	antituberculosis
trimethoprim	antibacterial
vidarabine	antiviral

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Physician's Hospital Privileges—Ebb and Flow

HAROLD L. HIRSH, M.D., J.D., F.C.L.M.

Membership on a hospital staff has become critical to almost every physician in this country. Hospitals invariably require membership on the staff as a prerequisite to the rendition of medical services by a physician to a hospital patient. Nowadays a physician who is not allowed to practice in a hospital is, for all practical purposes, denied the opportunity to practice medicine. The structure of the health care system in this country is such that there are situations in which a physician can wrongfully be denied the right to practice his profession and have no way to remedy the situation other than redress to the courts. There are other instances in which the available legal remedies were and are inadequate and provide no relief to the aggrieved physician.

In the last two decades, the courts generally are recognizing the ominousness of the situation and have become sensitive to the omnipotence of hospitals in this area. To that end, they have provided forums for disenfranchised physicians who were denied or deprived of staff appointments, and invoked appropriate remedies.

From the legal aspect, the endangering has come about as a result of judicial decisions, particularly the imposition of "corporate liability." In addition, there is Congressional and state legislation requiring hospitals to properly select and monitor physicians' activities. In some instances, hospitals have misunderstood their role in interpreting and implementing their legal duties. In other circumstances, they have deliberately abused and oppressed physicians because of their administrative zeal and greed.

In admitting a physician to its facilities, the hospital places a stamp of approval on him in the eyes of the public. Courts generally have now accepted the proposition that a physician's personality, including cooperation with the hospital administration and staff, as it affects the standard of care provided by the hospital, is one of the criteria to be taken into account in the granting or renewal of staff privileges. Thus, it is within its rights to consider personality factors in its selection appointment and removal decisions. The courts have upheld a hospital's right to require a physician applicant, as a condition for privileges, to document not only his experience, training, and demonstrated competence, but his adherence to the ethics of his profession, a good reputation, and his ability to work with others, with sufficient adequacy to assure the medical staff and governing body that any patient treated by him in the hospital would receive a high quality of medical care. Hospitals are now required to evaluate and to monitor by regular review a physician's physical and mental competence, attitudes, and dedication, as well as his ability to get along with others in their institution and elsewhere. This becomes critical to a physician, who can now be denied hospital privileges for failure to maintain adequate records in a timely fashion, or inability to get along with his health care associates.

Courts have upheld boards of trustees wishing to terminate antagonistic and uncooperative, as well as incompetent physicians. The rationale here is that upsetting normal hospital function is not conducive to optimum patient care, which it is the board's responsibility to maintain. The hospital is no longer merely the physician's workshop. Since the law now deems it a health care provider as well, the hospital, through the board of trustees, is primarily responsible for the quality of patient care. To fulfill this duty, it is essential that they make careful and proper selections of those who will have privileges at their institution. For even though patients select their own physicians independently, the hospital will in effect have endorsed their attendings as competent. Once the patient enters the

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hospitals, the responsibility extends beyond the providing of room, board, equipment, and so on.

Annual applications for privilege renewals must be carefully scrutinized and evaluated. This process has become more rigorous in recent years and JCAH accreditation regulations require renewal candidates to produce relevant records, and undergo both physical examinations and personal interviews or discussions. In addition, the hospital must continually monitor less tangible qualities, such as dedication and reliability, in each attending staff member.

Most of the litigation dealing with medical staff privileges does not allege violations of the statutory law, but instead alleges either arbitrary, capricious and otherwise discriminatory conduct violating due process and equal protection or tortious interference with the physicians' business relationship with his patients. Until recently the courts have generally not been willing to interfere with hospital board's decision and substitute their judgment for that of the board members. This is no longer viable. Courts are now beginning to consider hospital privileges as a fundamental vested right, rather than a privilege bestowed by the hospital administration. The law giveth and the law taketh; in response to these transgressions the courts have intervened on the physician's behalf protecting his status in the hospital.

Civil Rights Act

In the last decade the courts have become sensitive to this fact and have provided forums for disenfranchised physicians who have been denied or have lost staff appointments. Where appropriate, the courts have come to the aid of the aggrieved physician by holding that any hospital which receives federal funds under the Hill-Burton, Medicare or similar legislation cannot discriminate on the basis of race, color or national origin in its medical staff appointments under the Civil Rights Act of 1964.

Due Process

As to the protection and preservation of the independence of the medical staff, it has been held that only the medical staff may promulgate and adapt the rules, regulations and by-laws under which they operate. The hospital board of trustees are restricted to approving these by-laws. Any insoluble conflicts are properly brought before the courts.

It has also been held that the governing board of a hospital must adhere to a minimum of due process in its staff appointments and thus cannot engage in the arbitrary and capricious exercise of its discretion. While this type of reasoning originally applied only to public hospitals, it has also been applied to a variety of cases involving private hospitals. Minimal due process considerations were applied to instances involving the withdrawal or reduction of staff privileges requiring that an adequate hearing be afforded the affected physician. The fiduciary obligation of the hospital to the public and physician requires a "fair procedure in staff membership situations."

More recently the courts had indicated that this includes the physician's right of access to all pertinent materials utilized by the hospital during the process as well as active participation of a lawyer during the proceedings. Minimal due process includes not only procedural but substantive due process. The punishment must fit the crime. The courts will now review complaints to determine whether the facts justify the adverse decision.

Discrimination for Economic Reasons

The courts generally provide adequate remedies where there is discriminatory or arbitrary treatment of a physician in staff appointments. Judicial relief, however, is often not obtainable in other situations where the harm to the physician, although perhaps as devastating, is of a more subtle nature and cannot be classified as capricious. These cases often involve situations where, for economic or personal reasons, various staff physicians without any opposition from the governing board of a hospital conspire to prevent another physician from pursuing his profession in a hospital. The conspiracy is cloaked in what appear to be legitimate circumstances. These cases usually fall into one of two categories: the conspiracy results in the denial or withdrawal of hospital staff privileges for the physician or the conspiracy effectively deprives him of the opportunity to practice at his hospital by limiting available beds for admission or operating room space and time.

Unfair Business Practices

Physicians have attempted to secure relief by relying on federal or state statutory protection proscribing unfair business or trade practices. Under these laws it is illegal for individuals or groups to conspire to prevent others from carrying on similar business competitively.

The courts have generally relied on two theories in denying relief based on a claim of conspiracy or unfair business practices. They have held that the medical profession is not considered a "business or trade" within the usual statutory meaning of the term; and the statutes are designed to redress an economic injury to the general public and a private individual is precluded from obtaining relief absent a showing of injury to the public in general. In light of the recent Supreme Court decisions which emphasized the "trade" aspects of the legal, dental, pharmaceutical and other professions, the theory in that the medical profession is not a "trade" no longer seems to be a compelling argument. There is no exemption from federal antitrust laws for the learned professions.

Voluntary, non-profit hospitals can no longer afford to rely on protection from suits under federal antitrust laws. Congress has held them to be sufficiently involved in interstate commerce to come under the labor relations laws. The Supreme Court has held the local hospital business sufficiently impacts on interstate commerce to place them within the jurisdictional reach of the federal antitrust laws.

Yet, recovery under these state and federal statutory schemes still requires an injury to the public in general. The federal statutes also require a showing of a "substantial impact upon interstate commerce." The physician, whose injury is largely a personal one in such a situation, will be hard put to overcome these barriers. It appears, however, that the courts will accept the premise that not only the physician but his patients, also suffer by his deprivation of hospital facilities. Do they constitute the necessary injured general public? A Michigan federal court decision appears to imply that they do. In a recent case, the Michigan federal court ruled that a physician had standing to sue a hospital for violation of the federal antitrust laws for restraint of trade in excluding him from staff membership if he could prove that a significant number of his patients receive Medicare or Medicaid benefits, despite the fact that both his and the hospital's patients were almost exclusively from a certain area of Michigan.

Civil Conspiracy

However, even without resort to statutory aid, the physician who is injured from a conspiracy to deprive him of his right to practice his profession is able to seek relief under the common law principle of civil conspiracy. Civil conspiracy is defined as a combination of two or more persons by concerted action to accomplish an unlawful purpose, or to accomplish some purpose not in itself unlawful by unlawful means. Recovery under this theory is often difficult to obtain primarily because it is necessary for the plaintiff to show that the defendants actually entered into an agreement or combination among themselves. In fact, this requirement has proven to be a roadblock to various attempts by physicians to seek recovery under a civil conspiracy change.

Faced with the situation of a legal wrong inflicted on a physician which would otherwise remain unremedied, the courts have begun to recognize the need for judicial relief, and are beginning to invoke the doctrine of civil conspiracy. The evolution of this philosophy undoubtedly was assisted by the recognition by the courts that health care professionals and deliverers of health services were for these purposes involved in a business or trade as a professional.

In essence, the courts had said that everyone has the right to establish, engage in, and conduct a lawful business (profession). To that end, they are entitled to the protection of organized society through its courts whenever that right is unlawfully violated. An actionable wrong is established against anyone who is said to have intentionally interfered with that right without justifiable cause or excuse. It is, therefore, an actionable wrong for two or more persons to conspire willfully and maliciously to injure and damage another in the conduct of that lawful business or profession. That includes the deprivation of hospital privileges, or the inability to practice because of the unlawful withholding of necessary medical assistance.

If the physician-plaintiff is able to prove that the defendants did act in concert to injure him, the civil conspiracy charge is a broad enough theory to encompass a variety of "wrongs" actionable at common law. In a California case the court stated that a cause of action was valid for common law restraint of trade where it was shown that the defendants, members of the governing board of a hospital and various staff physicians, entered into a conspiracy to intentionally interfere with the plaintiff-osteopath's business by denying him staff privileges. Likewise, in a Missouri case the court employed a civil conspiracy theory to uphold a complaint of interference with the contractual rights between plaintiff and his patients. The physician was able to prove that several physicians and the hospital's governing board conspired to prevent him from acquiring membership on the hospital staff.

The flexibility of the legal theory of civil conspiracy in hospital staff cases is demonstrated in a recent Florida case. The surgeon-plaintiff brought suit against a hospital and all the staff anesthesiologists alleging a conspiracy to refuse to provide him anesthesiological services. This resulted in his financial ruin. The court recognized the dilemma of the surgeon and certified the civil conspiracy charge as a valid theory of recovery. It emphasized that civil conspiracy may entitle an individual to relief by virtue of the defendants' concerted action even though an anesthesiologist has the legitimate right to refuse to render his services to a surgeon, where all the anesthesiologists of a hospital agree to refuse their services to a competent staff surgeon, this conduct amounts to an effective deprivation of the surgeon's practice at the hospital. This gives rise to an independent wrong under the concept of civil conspiracy. The court's reasoning enhances the ability of an aggrieved physician to recover under a civil conspiracy theory. It is the product of a court sensitive to the dilemma of a troubled physician whose injury is subtle and the product of action which seems legitimate, but is nonetheless intentional and devastating. It recognizes the pivotal economic nature of a physician's hospital practice.

The right of a physician to practice his profession in a hospital unmolested financially is succinctly stated in another recent case. The court held that everyone has right to establish and conduct a lawful business or engage in a lawful profession, and is entitled to the protection of organized society, through its courts, whenever that right is unlawfully invaded. An actionable wrong is established against anyone who is shown to have intentionally interfered with that right, without justifiable cause or excuse. It is, therefore, an action-

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able wrong for two or more persons to conspire maliciously and without justification or excuse or injure or damage another in the conduct of a lawful business or profession. Faced with the situation of a legal wrong inflicted upon a physician, which might otherwise remain unremedied, courts have recognized the need for judicial relief and have invoked it under the common law doctrine of civil conspiracy.

Staff Appointments and Hospital Prerogatives

Hospitals' decisions to enter into exclusive contracts for some medical services by granting exclusive privileges to only one or a few physicians have generally been upheld by the courts as good faith attempts to insure competent quality medical care. Antitrust laws have been held not to have been violated by such contracts granting exclusive rights to practice a medical specialty, such as cardiology and dialysis, when the contracts were not unreasonable.

Hospitals may restrict privileges if the hospital services would be overtaxed. Furthermore, a hospital's governing board has the power to require consultation even of a specialist, in the interest of quality care. An Ohio court has held that certification, or eligibility, or membership in the specialty association, or a minimum period of experience, may be required for granting major surgical privileges in a hospital. This was not unreasonable or arbitrary. A hospital may also require all staff physicians to maintain adequate malpractice insurance, because the governing board must maintain the fiscal integrity of the hospital for the benefit of the patients.

A hospital will not be violative of federal antitrust or state unfair business practice laws if it enters into an agreement with another hospital to restrict certain services and obtain or retain others in order to avoid duplication of services and improve quality of care when it is subject to a federal or state regulatory agency requirement. Absent this requirement, such a voluntary agreement would be suspect when viewed in light of federal antitrust and state unfair business practice acts. This kind of an agreement would be legal if the hospital included community members in the planning and decision.

Recent decisions have expanded the scope of antitrust actions in health care delivery. A court recently ruled that a hospital's medical staff may not assert immunity defenses under the antitrust law for various activities that were alleged to have constituted antitrust violations, interfering with the functioning of an abortion clinic. A Blue Cross-Blue Shield plan in Texas was held to be subject to Sherman antitrust violations in giving preferential reimbursement to subscribers who filled prescriptions in pharmacies who were contractual providers of Blue Cross-Blue Shield as compared to non-contractual pharmacies.

Conclusion

Hospital health care is a triangular arrangement between patient, physician and hospital. It can become an illicit love triangle. Now the courts will intervene because medical practice may be considered a "business or trade" and hospitals do impact on interstate commerce. The courts have recognized that a physician without hospital privileges is like a fish without water.

Life need not always be unfair for the physician vis-a-vis his right to practice in the hospital. The law has imposed upon hospitals the duty of properly selecting and monitoring its attending physicians' "corporate liability." On the other hand, it has also protected the practitioner by requiring the hospital to adhere to constitutional fair play and equal protection under the civil rights laws, to procedural and substantive due process, and adherence to the federal and state unfair business practice acts. Depending on the circumstances, relief under the common law doctrine of civil conspiracy, state unfair business practice and federal antitrust laws may be available to physicians who are disenfranchised by hospitals in their capacity as members of the medical staff.

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Month in Washington

The Senate Finance Committee continues to forge ahead with its consideration of a catastrophic national health insurance proposal with Chairman Russell Long (D-LA) determined to secure a favorable vote.

However, the shadow of the budget-balancing imperative has made committee members cautious about actions that would increase federal spending next year. As a consequence, committee approval of a NHI bill, while a giant step forward, would leave NHI still a long way from adoption by Congress, the formidable hurdles of Senate approval, and action by the so-far disinterested House standing in the way.

A majority of witnesses appearing before the Senate Finance subcommittee on Health have endorsed the spurring of competition in the health care field, but most expressed some reservations about the so-called "pro-competition" measure before the panel.

Lowell Steen, M.D., Board Chairman of the American Medical Association, said the AMA supports the principle of increased competition through multiple insurance options for employees. However, Dr. Steen cautioned that "any legislation embodying such principles must also carry sufficient safeguards to protect the purchaser . . . also we must never let quality be sacrificed to cost considerations."

The pro-competition proposals bring new considerations to the debate over national health insurance, Dr. Steen noted. "The goal of this legislation is to lower national expenditure for health care by assuring options of coverage to employees under employer health plans . . ." The current tax deduction for premium purchase and for individual medical expense costs would be sharply curtailed under these proposals in an effort to force employers and individuals to seek lower cost plans, including health maintenance organizations.

Dr. Steen said the vast majority are protected by health insurance, but there are some who through no fault of their own cannot obtain the coverage they need. "These new proposals (pro-competition) are not designed to deal with this problem, and in some ways . . . may even exacerbate it," he told the subcommittee.

The present tax relief for employee health insurance benefits has been spectacularly successful in encouraging health insurance, he noted.

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He said changes that should be made in the private insurance system that would go a long way to close the gaps in coverage include minimum standards of adequate benefits, with appropriate deductible and co-insurance; a simple system of uniform benefits by federal, state and local governments for those unable to provide for their own medical care; and the purchase of private catastrophic coverage.

"A nationwide program could be instituted by the private industry (and government if necessary for reinsurance) to make available catastrophic coverage to protect against the impact of a costly illness that could be economically devastating. We call upon the committee to consider these points when reviewing any health insurance proposal."

Referring to the bill before the subcommittee, sponsored by Sen. Dave Durenberger (R-MN), Dr. Steen said the bill contains no mandate that the employer provide any insurance, and the employee's participation in any plan would be voluntary.

"The AMA supports competition in the delivery of medical services," said Dr. Steen. "Competition at its best can raise the quality of care and reduce the costs of providing that care. Such competition is promoted in the Durenberger Bill in the requirement of multi-plan options, but there are also limiting conditions . . ."

One problem is that current law already requires the option of comprehensive benefits provided by an HMO. Since there would be no corresponding broad coverage requirement for conventional insurance in the bill, competition could suffer, according to Dr. Steen.

He pointed out that the concept of increased competition through limitation on the tax exclusion by employees with respect to employer-paid premium and a system of cash rebates for low-cost plan selection was contained in a recommendation of the National Commission on the Cost of Medical Care—a recommendation that has received AMA approval.

"However, we have reservations about a program that might encourage the individual to acquire less coverage than is desirable," said Dr. Steen.

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Government support for medical education is needed to bridge the gap between the limits of private resources and the costs of medical education, the AMA has told Congress.

Noting that legislation has been introduced to eliminate capitation grants for medical schools, the AMA said such aid "has been a valuable investment of public funds to improve the quality and availability of medical education." Medical schools use these funds according to their specific needs and the needs of their communities, the AMA noted.

C. William Ruhe, M.D., Senior Vice President of the AMA, testifying on the opening health manpower hearings of Congress before the Senate Human Resources Health Subcommittee, said that loss of general institutional support would cause schools to seek other sources of funds, possibly through tuition increases, and harm the quality and availability of medical education.

In addition to general support, special project grants serve to influence directions in medical education, Dr. Ruhe said. "With special project grants each institution may judge whether it can and should participate, based on factors such as curriculum strengthening, community needs, as well as other factors."

The AMA official endorsed a system of government guaranteed loans, along with interest subsidies, as the most effective means of generating funds for modernization of schools from private money markets.

The AMA also supported special assistance for schools with financial problems that threaten the quality of their programs and their continued operation. "Such assistance, however, should not become a permanent crutch for faltering schools," Dr. Ruhe said. "Rather, it should be geared to overcoming immediate financial hurdles and lead to financial stability."

On the question of student aid, "We are deeply concerned by the financial pressures placed on students, and we firmly believe that access to medical education must not be allowed to become limited on the basis of income."

He noted that the AMA, through its foundation, operates its own loan guarantee program for medical students and resident physicians. Since the inception of this program in 1962, more than $95 million in loans have been guaranteed.

"Our resources, however, are not sufficient to meet an ever growing demand in the face of rising tuition costs," Dr. Ruhe said. "It is essential that government at all levels take steps to assure students continued access to adequate resources.

"Student assistance must be of the highest priority for government action . . . effective mechanism for government participation is a program of guaranteed loans," Dr. Ruhe said. Such a guarantee serves to minimize the strain on government resources and also enhances the ability of students and newly licensed physicians "to make intelligent career choices according to their interests and capabilities," the AMA official said.

The AMA also supports other aid. For example, contractual service arrangements (between students and resident physicians and organizations such as the armed forces or other governmental services) are one option. Scholarships for exceptional students should be encouraged. And, financial grants-in-aid, without obligations for repayment, should be available for economically disadvantaged students. "We encourage both the states and the federal government to make these kinds of options available so that students can make choices according to their needs and abilities."

New physicians should be free to choose to repay a government loan directly, or to participate in a program of service in some needed area in lieu of payment, Dr. Ruhe testified.

The AMA supported the continuation of the National Health Service Corps "as a beneficial method of providing medical services in underserved areas."

The AMA also endorsed continued federal assistance to programs of basic nurse training, adding that federal assistance should be provided to the training institution as well as to the student.

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The AMA and other partners in the Voluntary Effort to contain health care costs have warned President Carter against pushing his long-stalled hospital cost-containment bill.

James Sammons, M.D., Executive Vice President of the AMA, told reporters following the White House meeting that he finds it "very hard to understand" why Carter opposes mandatory wage-price controls but favors hospital cost-constraints.

"In 1978 and 1979 doctors' fees have increased at a lower rate than the Consumer Price Index," Sammons said. "That says to us we're doing it voluntarily."

However, the White House rejected the advice. "We will continue to press for hospital cost containment," said White House Press Secretary Jody Powell. "If you just look at health costs over the past several months, that is an important area to which inflation has spread."

The cost containment bill was watered down into a voluntary program in the House last year and never made it to the Senate floor.

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On the staff of Middlesex Memorial Hospital, Middletown since 1948, presently in the Department of Family Practice. Medical society activities have included: Vice President 1957, and President 1958, of Middlesex County Medical Association. Delegate from Middlesex County to the Connecticut State Medical Society for many years; Counselor to the Connecticut State Society from Middlesex County 1973-78; Vice President of the Connecticut State Medical Society 1978-79 and President Elect 1979-80; served on the State Medical Society Judicial Committee, Statewide Medical Planning Committee, Committee for Liaison with the State Welfare Department, as a member of the Board and as President of the Middlesex County Heart Association, and on the Boards of the local Cancer and Tuberculosis Associations.

The President's Page

Several years ago the Federal Trade Commission instituted a suit intended to remove medical society restrictions against advertising by members. Our legal advisors recommended deletion of the prohibition against solicitation of patients from the "Principles of Medical Ethics" in order to better our position in the suit. More recently, suits by chiropractic associations, now rendered legally legitimate by state licensing, led to further legal recommendations and deletions. Faced with these and other major changes, the A.M.A. created a special committee to revise the Principles. The committee proposed new "Principles of Medical Ethics" which were received with mixed reaction by the House of Delegates. These Principles are now being reviewed by the state societies and are to report to the House this summer. Opposition to the new Principles seems to stem mostly from the decreased emphasis on the physician-patient relationship.

As far back as history is recorded, physicians have recognized the unique importance of the physician-patient relationship. In few other instances does one individual entrust to another such immense powers over life and welfare. Physicians have responded positively to this trust as typified by the Hippocratic commitment: "The regimen I adopt shall be for the benefit of my patients according to my ability and judgment and not for their hurt or any wrong . . . ."

Our own "Principles of Medical Ethics" has been primarily concerned with physician responsibility to the patient. Adherence to high levels of physician conduct prescribed by such codes has been the principal source of pride in our profession and of the high level of confidence in the individual physician so often demonstrated by the public. A few decades ago, these principles sought to discourage practices which might deter the physician from full devotion to the patient's welfare. Third party employment, splitting fees, ghost surgery and association with cultists were thought to impose a conflict of interest between the patient's "regimen" of care and the physician's financial welfare. As social and political changes placed more physicians in positions with responsibilities to third parties, the profession's response was to drop the now inadequate prohibitions, instead of developing stronger, more appropriate guides that might support physicians caught between the demands of third parties and the needs of their patients.

While our "Principles of Medical Ethics" has been growing weaker and less effective, science and society have been creating new demands for moral, ethical and political decisions involving patient-physician relationships.

No longer is "ability and judgment" the simple matter it was in the days of Hippocrates, or for that matter even a half century ago. The explosion in medical knowledge now requires immense and continued learning by every physician. Progress has also created new areas of ethical, moral and political decisions, such as: "Death with Dignity", artificial fertilization, fetal diagnosis and medical abortion, terminal care and life sustaining measures, and many more in the field of bio-ethics. The physician's role in making these decisions needs definition, particularly in terms of the physician-patient relationship.

Once the concern only of physician and patient, the financing of medical care has undergone changes even more dramatic than the scientific explosion. The role of third party payors and burgeoning legislative and regulatory controls over both physician and patient, have immensely complicated physician-patient relationships. The physician's responsibility for child care, until recently solely the parents prerogative, has, through court decisions, child abuse and neglect laws, and other legislation, now become largely a direct responsibility to the child. Rights of senior citizens are rapidly being eroded, primarily through federal control and state welfare regulations.

An interesting aside is that when our State Judicial Committee recently met to prepare the Society's position on cost-benefit, not one person suggested that we refer to the "Principles of Medical Ethics". Surely, the answer to such questions should be clearly available in the "Principles". Interestingly, the major section of the proposed statement is an almost exact restatement of the section of the Hippocratic Oath quoted above.

The "Principles of Medical Ethics" is not expected to be a creed to be imposed on all physicians, nor should it be a statement of absolutes, nor is it enough to enunciate a set of personal morals and ethics. Some of our profession undoubtedly feel that patients should have their medical care provided by the government and some, undoubtedly, that physicians should practice as dictated by government. The vast majority of physicians, and of the public as well, expect that physicians will strive to protect the physician-patient relationship. Surely our Societies can develop a set of medical ethics built around the concept of physician-patient responsibility, which clearly define the role of the physician in the many ethical problems of today, as well as new problems which the future will present.

W. Raymond James, M.D.
President

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Reflections from the Dean's Office

Quattrocento and the Twentieth

ROBERT U. MASSEY, M.D.

If a fifteenth century physician were to be translated through a half millennium to our century, he at least would recognize a university. A visiting faculty member made this assertion to me last month while we talked, as aging physicians are inclined to do, of transient fashions and enduring values. It is so difficult to see into the mind of the past that I could not help him to pursue that train of thought further, and I decided to come back to it later, by myself.

There are several things about a university that a fifteenth century scholar would recognize, especially in the springtime at commencement. The robes are medieval and so is the mace, but on the surface there is little else from the Renaissance or the Middle Ages. The titles and degrees are ancient even if the language is not, and some university buildings almost everywhere are Tudor Gothic.

A fifteenth century visitor would feel much more at home during the service of one of the liturgical churches, providing it was not too reformed, and he would certainly recognize a library and maybe even a hospital. There is much of the physical Middle Ages that remains in our western world, especially in the European part; in fact, the Middle Ages, Renaissance, and Modern Times may all blur so that future students will lump the whole second millennium together in their minds, finding distinctions as hard to recall as we do when we think about the first.

Medical schools in Italy began to be parts of universities in the fourteenth and fifteenth centuries, but at Paris, Oxford, and Cambridge, full-time faculties with university support did not develop until the following century. German medicine flowered in the second half of the nineteenth century, and American medicine, following the German model, came alive in the twentieth. An academic medical center in Farmington or Hershey is not much like fifteenth century Padua or Bologna, but is remarkably like its twentieth century counterpart in Hannover or Rotterdam. They all have roots going deep into the culture that formed around the shores of the Mediterranean three thousand years ago. There are continuing traditions and institutional memories. Commencement and the awarding of the old degrees according to ancient formulae; the robes and hoods and funny hats; the procession with mace and banners; the venerable oath taking—all witness to our Latin, Greek, and Hebrew origins.

The fifteenth century visitor would know that he was still in a European world and, I suspect, would find some modern universities more like the Paris or Padua of his day than anything else, except churches and maybe law courts and nursery rhymes.

Our problem is that we can not know how great the differences are; we are too close in time to know whether the similarities are deep and the differences only on the surface, or whether it is the other way around. Chaucer delights us with the freshness of his portrait of the Doctour of Phisyk, while commencement addresses from the sixties seem hopelessly outdated. Close-up, transient fashion is hard to distinguish from enduring value; anyway, the distinction may be nonsense if the relativists have their way about values.

I mentioned Osler to a young faculty member recently and talked of Semmelweis to another. Neither had heard of them. In a discussion of medical education, I recalled that both Japan and the new medical school in Baltimore had adopted the German model following the Franco-Prussian War. That Japan had been a feudal society in the first half of the nineteenth century, or that there had been a Franco-Prussian War, were both new to a young physician who was also unclear about Flexner.

If we manage to scuttle our collective memory in these latter days of the twentieth century, and if our picture of the past loses not only perspective but definition and color, the third millenium could turn out to be either a brave new start or a deadly surprise.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Physicians' Obligations to Maintain Privacy and Confidentiality II: Recent Cases

JOSEPH M. HEALEY, J.D.

The difficulties encountered by physicians in identifying and satisfying their obligation to respect confidentiality and privacy in the doctor-patient relationship are particularly troublesome in cases involving mental health treatment. Two recent cases have addressed various aspects of these difficulties. Though neither of the cases occurred in Connecticut, each represents issues of concern to all physicians and deserves consideration during our continuing exploration of confidentiality and privacy.

In 1978, the Hawaii legislature, eager to reduce medicaid fraud and abuse, enacted a statute which required medicaid providers to maintain records of services provided and which allowed inspection of the records by state agents subsequent to the issuance of an administrative inspection warrant. Virgil Willis Jr., a licensed clinical psychologist and the Hawaii Psychiatric Society (the district branch of the American Psychiatric Association) challenged the constitutionality of the statute and sought to prevent examination of psychiatric records under its provisions.[1] They claimed that the statute violated their right to be free from unreasonable searches and seizures guaranteed by the Fourth Amendment and their rights and the rights of their patients to privacy guaranteed by the Ninth Amendment. In reviewing these claims, the United States District Court for the District of Hawaii acknowledged that the constitutional right of privacy involved two related concepts: an interest in independent decision-making (autonomy) and an interest in avoiding disclosure of sensitive information (confidentiality). Though each was considered important, neither was considered absolute. Under certain circumstances if the state were capable of demonstrating a compelling interest, the constitutional rights involved could be limited. In the case at hand, however, the Court was unconvinced that such an interest had been demonstrated:

> "The State has a compelling interest in ensuring that services and supplies for which it is being billed have been provided, and that the medicaid program is not being defrauded. But Section 8 is not narrowly drafted to express only those State interests. There has been no showing, and the court does not believe that there could be a showing, that the issuance of warrants to search and seize the therapeutic notes, patient history forms, diagnoses, and other confidential medical records of a psychiatrist, absent even a suspicion that an individual provider has defrauded the State or failed to maintain records, is necessary to serve any of the State interests put forward."[2]

In considering the issue of reasonable searches and seizures, the Court concluded:

> " . . . the privacy interests of both a psychiatrist and his patient in the psychiatrist's confidential medical files are very important. Confidentiality of psychiatrist-patient communications is essential to preserve an individual's freedom of choice in deciding whether to seek psychiatric care, to encourage a patient to volunteer sensitive personal information in the course of treatment, and to enable a psychiatrist to conduct such treatment in the best possible manner . . . The psychiatrist whose office and records are searched has a Fourth Amendment expectation of privacy in the medical files even though the patients themselves may not have such reasonable expectation as to records they do not possess."[3]

JOSEPH M. HEALEY, J.D., Assistant Professor of Community Medicine and Health Care, University of Connecticut; School of Medicine, Farmington, CT.

The Court enjoined execution of the Act and ordered the State to deliver to the Clerk of Court all records of Dr. Willis seized during the administrative search.

A contrasting line of cases has been developing during the past few years in which the duty of the physician to maintain confidentiality is found to be outweighed by the interests of identifiable third parties. These cases involve the liability of therapists, including psychiatrists, for failing to warn third parties or potential victims of danger or threats of potential harm by persons to whom they render treatment or therapy. In such cases, therapists argue that they owe a primary duty to their patients, that to make any disclosure of information obtained during the therapeutic process would undermine the trust and confidence essential for successful therapy, that even if disclosure were acceptable, the therapist has only a limited ability to predict the conduct of a patient/client and is not capable of discerning in each case real threats from exaggerated claims. In the case of *McIntosh v. Milano,*[4] the Superior Court of New Jersey rejected these arguments and recognized a duty of the physician to disclose information:

> "To summarize, this court holds that a psychiatrist or therapist may have a duty to take whatever steps are reasonably necessary to protect an intended or potential victim of his patient when he determines, or should determine, in the appropriate factual setting and in accordance with the standards of his profession established at trial, that the patient is or may present a probability of danger to that person. The relationship giving rise to that duty may be found either in that existing between the therapist and the patient, as was alluded to in *Tarasoff,* or in the more broadly based obligation a practitioner may have to protect the welfare of the community, which is analogous to the obligation a physician has to warn third persons of infectious or contagious disease.[5]

As these cases suggest, it is not always self-evident how physicians should satisfy their obligations to both patient and society.

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2. *ibid.,* pp. 16-17.
3. *ibid.,* pp. 29-30.
4. *McIntosh v. Milano* No. L-44368-76 (Superior Court of New Jersey, June 12, 1979).
5. *ibid.,* pp. 26-27.

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EDITORIALS

Increasing Testicular Cancer Incidence in Connecticut

Urologists in Connecticut have noted that testicular cancer seems to have become an increasing part of their practices. Most of the patients have been under age 45. This clinical impression of rising incidence of the disease is now confirmed as a state-wide trend by the Connecticut Tumor Registry. (Table 1) The age-adjusted rate for testicular cancer rose gradually from 1.77/100,000 males in 1935-44 to 2.99 in 1965-74. In the next 3 years it jumped to 3.88. This dramatic rise was attributable almost entirely to increased incidence in men aged 15-44. The incidence pattern in Connecticut is now similar to that observed 15 to 20 years ago in Denmark, especially in Copenhagen, and in urban Norway.[1] Peterson and Lee also noted that age-adjusted testicular cancer mortality rose gradually in England and Wales from 1911 to 1969. The age pattern, however, was one of declining rates in older men concurrent with more than compensatory increases in rates among men 15-44. They postulated a genetically susceptible fraction of the male population among whom this cancer might develop at any age. Changes in environmental promoting factors might cause earlier appearance of the cancer.[1] Age and time trends in Connecticut have been compatible with this hypothesis.

Table 1

TESTICULAR CANCER
INCIDENCE RATES PER 100,000 MALES
CONNECTICUT 1935-77 (By Age and Time Period)

	Time Period					*All*
Age	*1935-44*	*1945-54*	*1955-65*	*1965-74*	*1975-77*	*years*
0-14	0.05	0.04	0.24	0.14	0.25	0.15
15-24	1.6	2.0	2.4	3.0	4.1	2.6
25-34	3.6	5.3	6.3	6.9	8.9	5.9
35-44	3.2	4.3	5.3	5.0	8.4	4.9
45-54	1.2	2.8	1.9	3.3	3.5	2.5
55-64	1.4	1.3	2.1	1.9	1.6	1.7
65-74	2.5	2.1	1.4	1.8	1.1	1.8
75-84	4.1	1.9	2.2	2.3	0.9	2.3
85+	0.0	0.0	0.0	4.1	4.3	2.0
Age adjusted[a]	1.77	2.36	2.7	2.99	3.88	2.64

[a] 1950 United States standard population.

The nature of the environmental promoters is unclear. There is evidence that the maternal estrogen levels to which a son is exposed in utero may influence his later development of testicular cancer.[2] Exogenous estrogens given to some Connecticut women to prevent abortion, during the two decades after about 1950, might have contributed to the current epidemic. However, the table shows that the rise in testicular cancer rates began in Connecticut before exogenous maternal estrogen could have played a part. Cohort analysis of 5-year incidence rates and 5-year time periods suggests that the birth cohorts born around 1940 and 1945 had notably greater incidence of this disease than their predecessors. Maternal fatness should be considered among prenatal influences because of the known relationship of obesity to estrogenic activity of women.[3] The smoking habits of mothers during pregnancy may be worth study because of the known influence of maternal smoking on the birthweight of infants.[4]

Undescended testis is a known risk factor in testicular cancer with relative risks estimated at 8-fold,[5] but there are no data to show whether this condition has changed in its rate of occurrence over the past century. The question whether increased temperature of the intraabdominal testis causes or contributes to the risk is not answerable from present information. Some of the risk in the undescended testis seems to be genetic, but if higher testicular temperature contributes to the risk, the relation of male dress styles should be included in etiological studies. History of surgery for inguinal hernia has also been associated with testicular cancer risk but the respondents could, perhaps, have reported as hernia what had actually been undescended testis.[5]

Host factors occurring later in life may play a role. Higher rates in married men were reported in two large studies,[6,7] with the suggestion that early sexual activity or venereal disease or both may be involved. Seminomas were positively associated with both cryptorchidism[5] and marriage.[6] There are no substantiated reports of cancer associated with personal use of drugs such as marijuana or with occupational exposure to drugs or other chemicals, but these possibilities merit consideration. In rats exposed to marijuana smoke, impairment of spermatogenesis has been reported.[8] Some pesticides are known to induce sterility and lead has been reported to cause changes in spermatogenesis and to be associated with Wilms' tumor in children of lead exposed fathers.[9] The size of the epidemic in Connecticut calls for prompt search for preventable causes of testicular cancer.

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Letters to the Editor

Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed by all authors, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.

THE ASSIGNMENT RATE: HOW HIGH IS GOOD?

To the Editor: The two articles in the February issue of *Connecticut Medicine* on the Medicare assignment rate are disturbing from a number of points of view. There is the continued implication that low assignment rates are "bad" and that high assignment rates are "good". There is the implication in the Blue Cross-Blue Shield article that Medicare recipients bear an unjust (implied) burden because of the low assignment rate in Connecticut.

The following points should find harmony in the philosophies of many if not most physicians:

1) CSMS should reiterate and stand by the 9 point program approved by the CSMS Council in August of 1977 and published in *Connecticut Medicine* Volume 41, No. 11.
2) The value of improving the administration of the Medicare program lies partially in making life easier for the patient for whom financial considerations *are* a burden and not just a responsibility.
3) It should be obvious that the physician's responsibility is to provide quality medical care, not to fill out forms and bear responsibility for being reimbursed for services; therefore, improvement in administrative details will serve the provider (oh, that wonderful word!) as well.
4) Any provider list of those who accept assignment hints of 1984 (we're getting close!) and suggests the possibility that the choice of physician may well be based on the relationship of that physician to BIG BROTHER, not on training, competence, et cetera. Physicians and CSMS cannot condone the birth of such a concept.
5) CSMS should battle openly and aggressively the implied notion that if a charge is more than the "allowable" charge, it is excessive.

Robert C. George, M.D.
Norwalk, CT

BOOK REVIEW

Living with Lung Cancer, A Reference Book for People with Lung Cancer and Their Families by Barbara G. Cox, B.S., David T. Carr, M.D., and Robert E. Lee, M.D. 95 pp. Mayo Foundation, Rochester, Minn. 1977. $2.55.

Here is a gentle and kindly book that is well-equipped to answer most questions patients and their families ponder when lung cancer is suggested or actually diagnosed. The fact that some cures occur and that life can usually be made comfortable and prolonged is emphasized. The way this cancer shows up and may spread is clearly stated with the help of diagrams. The psychological impact, ways of alleviation, and where in general to seek help is explained. The major diagnostic and treatment methods are simply described. Complications of all treatments are also described and the authors manage all this without bias or advocacy of any particular regime. There is a skimpy chapter on principles of nutrition and an excellent exposition of the philosophy behind unproven treatment methods (quackery). A glossary and index increase the usefulness of this reference manual. Such a volume can decrease people's anxieties, save nurse and physician time, and encourage better communication focusing on areas where additional explication is desired.

John L. Pool, M.D.
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COUNCIL MEETING

Thursday, April 3, 1980

Attendance

Present were: Drs. Kamens, James, Canzonetti, Backhus, Mendillo, Sadowski, Freedman, Hess, Van Syckle, Fabro, Friedberg, Rubinow, Anderson, Magram, Parrella, F. Barrett, Zlotsky, Jameson, Beck, Abbot, Seide, Shenker, Eslami, Tierney, Bobruff and Sonnen.

Also present: Dr. Sharon, Mr. Norbeck and Mrs. Lindquist.

Approval of Minutes

It was VOTED to approve the minutes of the meetings of February 13, 1980, and March 12, 1980, with the following amendment made on Page 3 of the minutes of February 13:

> "That the Committee on Legislation not Professional Liability was granted permission to continue to study the feasibility of mandatory screening panels, etc. . . . "

Elderly Health Screening Program

After discussion of the report of the Ad Hoc Committee, it was VOTED to approve the report and to recommend to the House of Delegates that the action taken on November 15, 1979 be reconsidered and that the following recommendations be adopted:

1. That the multiphasic screening program of this group, the Elderly Health Screening Program, has much to recommend it. However, the ad hoc committee was very concerned about the way in which the information was dispensed and the professional liability of the practitioner to whom such patients and data were referred. It was the feeling of the ad hoc committee that the Council should recommend to the House of Delegates that it reconsider its action on the subject and that the following points should be stressed to the Elderly Health Screening Council.
   - a. That it is the responsibility of the individual person who seeks the service of this elderly health screening program to secure the data and to implement the recommendations of the screening group.
   - b. That the screening group is under the obligation to see to it that those persons seeking its services shall be properly notified as to the results of such screening in one of the following ways:
     1. That the individual has abnormalities.
     2. That no abnormalities were found.
   - c. In the case where abnormalities were found, it would then be the responsibility of the screening group to provide the individual with the documentation and recommend to the person that they seek medical attention. It is then the responsibility of the individual person to seek medical attention bearing the data with him.

     That it not be the practice of the screening group to send to the physician the results of the screening examination or the screening material.
   - d. In the case where no abnormalities were found, the individual should be notified of that fact, and also be informed that this screening was not to be considered a complete physical examination. (It might be pointed out that we understand that this is the policy of the screening group.)

It is the strong feeling of the ad hoc committee that the Committee on Public Health be provided with the charge that it have an ongoing concern and interest in multiphasic screening and, also, that all screening programs be strongly urged to secure physician input into the program both in the planning and execution phases of the program.

New London Foundation For Medical Care (NLCFMC)

Following a discussion of the New London County Foundation For Medical Care's effort to implement an HMO-IPA, it was VOTED to support the application of the NLCFMC for a planning grant from HEW.

Medical Student and Postgraduate Physician Membership in CSMS

In an action at its meeting on February 13, 1980, the Council VOTED to approve "the concept of medical student and intern/resident representation in the CSMS House of Delegates and that the Subcommittee to Revise the Bylaws be instructed to report back to the Council with an appropriate mechanism to achieve this goal." The Subcommittee to Revise the Bylaws met on March 20, 1980, and submitted a report to the Council for its meeting on April 3. Following lengthy discus-

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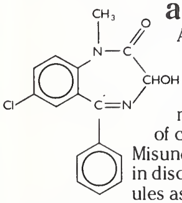

A study of compliance patterns reveals that more than 6 out of 10 patients made errors in self-administration of prescribed medication, largely due to lack of comprehension.* Misunderstanding of directions resulted in discrepancies in dosage schedules as well as in length of therapy. Since evidence suggests that expanded verbal instructions may encourage compliance, the patient receiving Valium can benefit from your explanation of the dosage regimen, what response to expect from therapy and when to expect it.

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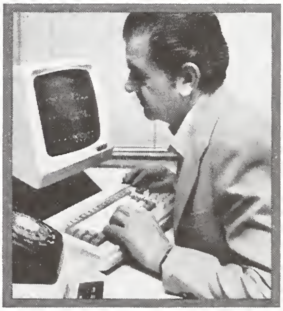

The time you devote to these explanations can be a therapeutic measure in itself. Most anxious patients respond to and benefit from a frank discussion with an objective, sympathetic professional.

At the start of treatment, establishing therapeutic goals helps the patient to learn *what* to expect and *when* to expect it. Patients should also be informed that the medication will be gradually reduced and discontinued upon attainment of the therapeutic goal.

Tapering of dosage is rarely necessary in short-term therapy, but when consistently higher doses are used for extended periods, patients should know that the gradual reduction of medication will be implemented in order to avoid sudden recurrence of symptoms or possible withdrawal symptoms. Such recurrence is unlikely when the causes of the anxiety have been worked out satisfactorily within your overall treatment program.

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It should be emphasized that there is no "magic" in any antianxiety tablet; that medication is not prescribed as a problem solver. Instead, Valium is being prescribed *as a temporary measure to relieve symptoms* generated by excessive anxiety and psychic tension.

* Boyd JR, *et al*: *Am J Hosp Pharm 31*: 485-491, May 1974

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Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation, usually limited to extended use and excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after continuous use, generally at higher therapeutic levels, for at least several months. After extended therapy, gradually taper dosage. Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

***Usage in Pregnancy:* Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed, drugs such as phenothiazines, narcotics,

Practical pointers on taking antianxiety medications

do's Patients should be instructed to keep to their dosage schedule exactly as prescribed. If they miss a dose, they should not try to make it up by taking two doses the next time. Ask them to contact you promptly if they experience worrisome side effects. Explain that drowsiness is a common reaction to almost all calming agents, but that it usually subsides in a few days. Urge the patient to contact you for a possible dosage adjustment if drowsiness or other reactions persist.

Just as you request a complete list of all medications the patient is taking, suggest that this list be given to any other physician treating her/him.

Like all medicines, Valium should be kept out of reach of children and young people. Old or unused medication should be discarded.

and don'ts Since drowsiness is an occasional problem, patients should be advised against driving or operating hazardous machinery until they see how the medication affects them. They should also know that tranquilizers increase the effects of alcoholic beverages, which should therefore be avoided. Also, warn patients against simultaneous use of drugs that depress the central nervous system, particularly sedative hypnotics.

Patients should be aware of the importance of not sharing their medications with friends and neighbors; they should know that what you have prescribed for them may be contraindicated for others.

• *2-mg, 5-mg, 10-mg scored tablets*

Valium® Ⓘⓥ

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An important adjunct to your treatment program for excessive psychic tension

barbiturates, MAO inhibitors and other antidepressants may potentiate its action Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies Observe usual precautions in impaired renal or hepatic function Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported. should these occur, discontinue drug. Isolated reports of neutropenia, jaundice, periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. *Adults:* Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d., adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. *Geriatric or debilitated patients:* 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) *Children:* 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

Supplied: Valium® (diazepam/Roche) Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10, Prescription Paks of 50, available in trays of 10.

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sion, it was voted to approve these Bylaws with minor amendments and to place them on the table at the HOD meeting on April 30 for action at a future meeting of the House of Delegates.

Public Information Program

After considerable discussion it was VOTED to trasmit the following report to the House of Delegates:

The Council spent a significant portion of two meetings in addition to a special session to study the charge of the House of Delegates to develop a Public Information Program and to carry out that directive. To that end, the matter was discussed with members of the Committee on Public Relations, and there was sentiment expressed in favor of an internal public relations program for the membership as well as the Public Information Program.

A number of public relations organizations were contacted, and the Committee heard a presentation from a large firm in March. The Council is not in a position at this time, however, to recommend a specific program. The House of Delegates is at liberty to charge the Council with any specifics that it may desire, but the Council recommends to the House of Delegates that the matter be referred to the Committee on Public Relations for review and a subsequent report to the Council.

Judicial Committee

a) *Cost Effectiveness and Medical Care:* It was VOTED to approve of the policy statement recommended by the Judicial Committee, as amended, and transmit to the House of Delegates for approval.

   The Judicial Committee of the CSMS expects that physicians will continue to be dedicated to providing the most appropriate treatment to patients, regardless of age, race, social or economic status, or their purported "value to society."

   The medical profession will continue to resist any system which places cost considerations before the patient's own best interest.

   It is expected that each physician will seek for each and every patient under his or her care the very best possible modality of diagnosis and/or treatment within that physician's power to provide, consonant with the state of the art and with the medical indications as understood at the moment.

b) *Recommendations for Revision of AMA's Code of Ethics:* Pursuant to the Council's charge, the Judicial Committee reviewed several proposed versions of the AMA Principles of Medical Ethics. It was VOTED to approve of the committee's recommendations as amended, and transmit to the House of Delegates for approval.

Professional Liability

It was VOTED to refer the communication from Fairfield County Medical Association relating to the newsletter on professional liability to the Committee on Professional Liability for evaluation and response.

Life Members

It was VOTED to accept for information the following list of Life Members:

Frederick R. Amore, New Haven (NH) - 1/1/80
Freeman F. Brown, Jr., Torrington (L) - 1/1/80
Rinaldo J. Cavalieri, Wethersfield (H) - 1/1/80
William A. Ellis, Hartford (H) - 1/1/80
Frederick C. Gevalt, Jr., Lakeville (L) - 1/1/80
Mark A. Hayes, Hamden (NH) - 1/1/80
Benjamin E. Lyons, Norwalk (F) - 1/1/80
Victor J. Mulaire, Stamford (F) - 1/1/80
John F. Reed, Hartford (H) - 1/1/80
James H. Root, Jr., Watertown (NH) - 1/1/80
Joseph G. Rossi, New Haven (NH) - 1/1/80
Hans Syz, Westport (F) - 1/1/80
Andrew H. Thomas, Manchester (H) - 1/1/80

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on April 3, 1980. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office, Tel.: (203) 865-0587. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street, New Haven, Connecticut 06511

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Physician's office suite on Burnside Ave., East Hartford, available at moderate rental. Contact Ms. Green, 233-3780.

We are seeking physicians or an emergency treatment corporation to own and operate emergency treatment facility in large Medical Office Building. Strong Demand. Contact Archie Damato, Medical Center, LTD., 131 New London Tpke., Glastonbury, CT 06033. (203) 659-1371.

FAMILY PRACTICE

The only Family Physician in a lovely southeastern Ct. town of 18,000 people wishes to retire from a well-established practice. Access to Thames River, L.I. Sound, industries and resorts. Positions of industrial physician, school physician, and medical examiner are open, as are privileges at two nearby hospitals. No charge for transfer of the practice. Home, office, land, furniture equipment and supplies available for lease or purchase, with owner financing available, as well as possibility of community encouragement. Contact 203-848-3414.

Director of Family Medicine Center—University-affiliated hospital seeks a bd. cert. or elig. FP with clinical experience to supervise the Family Medicine Center and serve as Associate Director of an established FP Residency Program full time. Excellent salary and fringes. Send resume to: Mr. A. Guido, Director of Personnel, St. Joseph Hospital, 128 Strawberry Hill Ave., Stamford, CT 06904.

Family Medicine or Pediatric solo practice: Dynamic, growing practice in cosmopolitan area of West Hartford. General pediatrics, convenient to hospitals and medical school. Good coverage. Available immediately. Excellent terms. Excellent nucleus for family physician(s) or pediatrician. Call 203-236-3084.

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Associate Medical Director needed by Electric Boat. Background in General Practice, Internal Medicine and/or Occupational Medicine desirable. Duties to include policy and program development, pre-employment physicals, periodic exams for special hazard exposure, preventive programs. Competitive salary comprehensive benefits, and relocation assistance. Send resume and salary requirements to J. Hardink. Supervisor, Dept. 642, Electric Boat Division, General Dynamics, Eastern Point Rd., Groton, CT 06340.

Director of new facility. Need to visit one hour per week at plant for Physicals and follow up treatment. Available for employee's office visits for emergency treatment prn and consultation. Office located in the Bridgeport, Stratford area, on staff of a Bridgeport Hospital. For further information call Edna K. Keyes, R.N., Bridgeport Fittings, Inc., P.O. Box 619, Bridgeport, CT 06601. 203-377-5944.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

ANESTHESIOLOGY

May '80. Age 33. AB-elig. MD and int.: India. Res.: Metropolitan Hosp., NY. Fellowship: Lenox Hill Hosp, NY. Grp., assoc. or institutional practice desired in CT. Contact CSMS/Anes.-VBS.

July '80. Age 32. AB-elig. MD and int.: India. Res. and fellowship: Westchester Med. Ctr. Grp. practice in large or med. community in CT. Rama S. Katragadda, M.D., Westchester Med. Ctr., Valhalla, NY 10595.

FAMILY PRACTICE

July '80. Age 30. FLEX. AB-elig. MD: Guadalajara. Int.: Brown Univ. Res.: Fairfax F.P. res. program, Med. Coll. of VA. Grp. practice in med. or sm. community near shoreline. Will consider others. No OB. 1-1½ hrs. drive to NYC or Boston. Interested in Southport area. James M. Lynch, Jr., M.D., 1623 Parkcrest Circle, #300, Reston, VA 32090.

July '80. Age 29. Conn. license. Nat'l. bds., cert. Presently in practice. MD: Einstein. Int.: Univ. of VA. Res.: Univ. of VA Hosp. Grp. or assoc. practice desired. Will consider solo. Prefers western CT. Contact CSMS/FP-JHR.

INTERNAL MEDICINE

Spring '80. Age 29. Nat'l. bds., cert. MD, int. and res.: Bowman Gray. Med. Sch. and affil. hosp. Grp. or assoc. type practice desired in CT. Richard G. Appel, M.D., 1620 W. First St., #93. Winston-Salem, NC 27104.

Cardiology: July '80. Age 31. AB-elig. MD and int.: India. Res.: St. Clare's Hosp., NY. Fellowship: VA Med. Ctr., Buffalo. Grp. or assoc. practice desired in CT. Contact CSMS/IM-Card.-MLB.

Hematology/Oncology: July '80. Age 39. AB-elig. MD: India. Int. and res.: Jamaica Hosp., NY. Fellowship's: VA Hosp., NY, Nassau Hosp., NY and Emory. Solo, grp. or institutional practice desired in CT. P.S. Balasubramaniam, M.D., 826-6 Clifton Ct. Ctr., NE, Atlanta, GA 30329.

July '80. Age 30. Nat'l. bds., elig. 6/80. MD: Univ. of Ill. Int.: Univ. of Minnesota Hosps. Res.: Northwestern Univ. Hosp. Grp., assoc. or institutional practice desired in CT. Raymond A. Colbert, M.D., 2717 N. Racine St., Chicago, IL 60614.

Cardiology: July '80. Age 28. Nat'l. bds., cert. MD: Downstate. Int.: Maimonides Hosp. Res.: Northport VA Hosp. Grp. or assoc. type practice desired in CT. Ira E. Kaplan, M.D., 523 E. 14th St., New York, NY 10009.

Pulmonary: July '80. Age 34. Nat'l. bds., cert.-IM; elig.-Pulmonary. MD: India. Int.: Mt. Vernon Hosp., NY. Res.: St. Francis Hosp., Trenton, NJ. Solo, grp. or assoc. practice in med. community. Akbar H. Obaray, M.D., 61-20 Grand Central Pkwy., Forest Hills, NY 11375.

Available now: Age 33. Nat'l. bds., cert. MD, int. and res.: UCLA. Also res.: Norwalk Hosp., CT. Interested in large grp. or assoc. practice and would definitely like to teach. Full time teaching would be most desirable. Kenneth L. Radack, M.D., 2371 Edgewater Dr., Napa, CA 94558.

Cardiology: July '80. Age 28. AB-elig.-(waiting results) MD: Pakistan. Int.: Beekman-Downtown, NY. Res.: Univ. of S.C. Sch. of Med. Fellowship: West PA Hosp. Solo, grp. or institutional practice desired in med. community near a Cath. Lab. Aftab A. Shaikh, M.D., 550B S. Trenton Ave., Pittsburgh, PA 15221.

May '80. Age 33. Conn. license. Nat'l. bds., cert. Presently in practice. MD: UConn. Int. and res.: Kaiser Hosp., San Francisco. Looking for grp. practice in Fairfield County. Will consider other opportunities in area or close by. Contact CSMS/IM-WHY.

OPHTHALMOLOGY

July '80. Age 29. Conn. license pending. Nat'l. bds., elig. MD: NY Univ. Int.: Nassau Cty. Med. Ctr. Res.: Long Island Jewish Hosp. Solo, grp. or assoc. practice desired in large or med. community. Desire assoc.-established practice or practice for sale. Edward A. Pulice, M.D., 49-20 Hanford St., Apt. #1, Douglaston, NY 11362.

July '80. Age 31. Nat'l. bds., elig. MD: Louisville. Int.: Henry Ford and res.: Sinai Hosp. both in Detroit. Fellowship: Glaucoma, Ochsner Hosp., LA. Grp. or assoc. practice desired in large or med. community. Robert M. Mandelkorn, M.D., 2518 Giuffrias, Apt. #218, Metairie, LA 70001.

OTOLARYNGOLOGY

July '80. Age 27. Nat'l. bds., elig. MD: Einstein. Int.: Montefiore Hosp. Res.: Greater Baltimore Med. Ctr. Solo, grp. or assoc. practice desired in CT. Dean A. Schaffer, M.D., 6914 Lachlan Circle, Baltimore, MD 21239.

PATHOLOGY

June '80. Age 34. FLEX. AB-elig. Presently in practice. MD and externship: Korea. Res.: Baptist Mem. Hosp., Memphis. Also interested in GP. Will consider all types of practice in CT. Contact CSMS/Path.-KSK.

Anatomic & Clinical: July '80. Age 36. Conn. license. FLEX. AB-cert. MD: Univ. of Bologna. Int. and res.: New Rochelle Hosp. Also res.: NY Med. Coll. - Flower & Fifth Ave. Hosp. - Metropolitan Hosp. Ctr. Grp., assoc. or institutional practice desired. Joseph V. Napolitano, M.D., 7 Howland Rd., Middletown, NJ 07748.

Immunopathology: July '80. Age 36. FLEX. Nat'l. bds., cert. MD: India. Res.: W.V. Univ. Fellowship: Cleveland Clinic. Grp. or institutional practice desired in large or med. community. Contact CSMS/Path.-SR.

PEDIATRICS

Aug. '80. Age 29. AB-elig. MD and int.: Pakistan. Res.: Kings County-Downstate, NY: Overlook Hosp., NJ. Fellowship: Children's Hosp., and V.W. Med. Sch., Milwaukee. Sub-specialty Allergy-Adult and Ped. Solo, grp. or assoc. practice in large or med. community. Malik M. Nasir Baz, M.D., 2535 N. Prospect Ave., #311, Milwaukee, WI 53211.

July '80. Age 38. Conn. license. Nat'l. bds., FLEX. AB-cert. MD: Far Eastern Univ. Int.: Elizabeth Gen., NJ. Res.'s: Jacksonville Hosp., FLA.: Long Island Coll. Hosp., NY. Fellowship: Roosevelt Hosp. Will consider all types of practice in CT. Contact CSMS/Ped.-JDB.

Ped./Adol. Med.: July '80. Age 29. Nat'l. bds., elig. MD: Georgetown. Int. and res.: Children's Hosp. of PA. Fellowship: Children's Hosp. of D.C. Grp., clinic or HMO in large or med. community. Thomas M. Pantino, M.D., 4017 Davis Pl., NW #2, Washington, D.C. 20007.

RADIOLOGY

Spring '80. Age 42. Nat'l. bds., cert. MD: Dalhousie. Int.: Victoria Gen. Hosp., Halifax. Res.: Queens Gen./L.I. Jewish Hosp. Presently in practice as ass't. Prof. in Rad. at Downstate. Experienced in Nuclear Med. and most forms of gen. diagnostic Rad. Will consider any form of practice. S. David Bogart, M.D., 79-39 210 St. Bayside, NY 11364.

Diagnostic/Nuclear: July '80. Age 34. Nat'l. bds., elig. MD: UConn. Res.: (Diag.) Hershey Med. Ctr. Fellowships: (Nuclear) Penn State; Hershey Med. Ctr.; Univ. of VT; Manchester Mem Hosp. Solo, grp. or assoc. practice desired in CT. Marc B. d'Avignon, M.D., 207 Bailey St., New Cumberland, PA 17070.

July '80. Age 49. Conn. license. Nat'l. bds., cert. MD: Tufts. Int.: Maine Med. Ctr. Res.: Walter Reed Army Med. Ctr. Well trained and experienced in ultrasound also special procedures. For the last 12 yrs. have had courses in pediatrics x-ray, urology, GI, isotopes, chest and ultrasound. Contact CSMS/Rad.-KWF.

RADIOLOGY - CONTINUED

Nuclear Medicine: April '80. Age 45. Presently in practice. Nat'l. bds., cert. MD: Downstate. Int.: Mt. Sinai Hosp., Cleveland and Jewish Hosp., NY. Res.: Montefiore Hosp., NY. Fellowship: John Hopkins Hosp. 13 yrs. clinical experience. Wishes to join Radiology grp. or multispecialty grp. in IM. Will also consider assoc. or institutional practice in large or med. community. Contact CSMS/Rad.-PAB.

May '80. Age 32. FLEX. AB-elig. MD: Guadalajara. Int. and res.: Mt. Sinai Hosp., NY. Solo, grp. or assoc. practice in CT desired. Donald S. Cohen, M.D., 1089 Briar Way, Ft. Lee, NJ 07024.

June '80. Age 32. Nat'l. bds., cert. MD: Penna State. Int.: White Mem. Ctr., CA. Res. and fellowship Univ. of Southern CA-Los Angeles Cty. Med. Ctr. Private practice: Civilian contact rad.: Tinker Air Force Base, Oklahoma City. Grp. or assoc. practice desired in med. community in CT. Thomas R. Fitzsimons, M.D., Bingen Rd., R.D. #5, Bethlehem, PA 18015.

Diagnostic: July '80. Age 31. Conn. license pending. AB-elig. MD: Guadalajara. Int.: Akron City Hosp., Ohio. Res.: Long Island Jewish Hosp., NY. Fellowship: NY Med. Coll. Diagnostic ultrasound including real-time. Wishes grp. practice in med. community. Robert S. Nuba, M.D., 73-23 210th St., Bayside, NY 11364.

SURGERY

July '80. Age 32. FLEX. AB-elig. MD: Paraguay. Int.: DePaul Hosp., VA. Res.'s: Long Island Coll. Hosp., Englewood Hosp., NJ, and Univ. of Rochester. Assoc. or institutional practice desired in med. community in CT. Albino F. Gimenez, M.D., 50 Knollbrook Rd., #12. Rochester, NY 14610.

Thoracic: Available now. Age 36. Nat'l. bds., elig. MD: Boston Univ. Int.: Einstein. Res.'s.: Stanford Univ., State Univ. of NY., Upstate. Fellowship: American Cancer Soc.; Stanford; Clinical, Thoracic Surg., Upstate. Looking for Univ. affil. hosp. or assoc. institution. Grp. or institutional practice in large community. Contact CSMS/Surg.-AMR.

Gen./Vascular: July '80. Age 30. FLEX pending. AB-elig. MD and int.: India. Res.: St. Elizabeth's Hosp., Mass. Grp. practice desired in med. community. Seeplaputhur G. Sankar, M.D., 128 Normandy Dr., Norwood, MA 02062.

July '80. Age 31. FLEX. AB-elig. MD: Bangladesh. Int. and res.: Bridgeport Hosp., CT. Grp. or assoc. type practice desired in CT. Life psychiatry resident in Newtown. Wishes to stay in CT. rather than relocate. Shafi A. Sultan, M.D., Bridgeport Hospital, Bridgeport, CT 06602.

July '80. Age 39. AB-cert./Gen. Surg.; elig./Plastic. MD: Ohio State. Int.: Akron Cty. Hosp., Ohio. Res.'s.: Wm. Beaumont Hosp., Royal Oak, Mich. and St. Louis Univ. Will consider all types of practice except industrial in med. or sm. community. Denis J. Winder, M.D., 326 Amend Ct., St. Louis, MO 63129.

July '80. Age 37. AB-elig. MD: Guntur, India. Int. and res.: Franklin Sq. Hosp., MD. Wishes solo practice in med. community in CT. Contact CSMS/Surg.-MAJ.

UROLOGY

July '80. Age 40. AB-elig. Res.: Mt. Sinai Hosp., NY. Grp. or assoc. practice in med. or sm. community in CT. Eliahu Koren, M.D., 5700 Arlington Ave., 6J, Riverdale, NY 10471.

July '80. Age 32. Conn. license. Nat'l. bds., cert. MD, res. and fellowship: Yale. Int. and res.: Mt. Sinai Hosp., NY. Solo, grp. or assoc. practice desired in large or med. community. Mark B. Osias, M.D., 12205 Morocco NE, Albuquerque, NM 87111.

July '80. Age 31. Conn. license pending. Nat'l. bds., elig. MD: NYU. Int. and fellowship: NYU-Bellevue. Res.: Kings County-Downstate. Assoc., grp. or solo practice in large community in CT. Contact CSMS/Urol.-GSR.

Cardiac Surgery at Yale—An Overview

ARTHUR E. BAUE, M.D.

The Yale Faculty and Yale-New Haven Hospital staff in cardiac surgery are pleased to respond to the invitation of the Editor of *Connecticut Medicine* and provide this review of cardiac surgery at Yale. Although the emphasis in the reports to follow will be on the experiences of our group at the Yale-New Haven Hospital, we will also provide comparisons of our experience with the state of the art in other centers. In this introduction it is my privilege to comment on the present status of cardiac surgery in general and on the specific presentations to follow. In this effort we are indebted to our colleagues in Cardiology—in adult Cardiology to Drs. Lawrence S. Cohen, Barry L. Zaret, Rene A. Langou, William P. Batsford, David Rutlen, Frans Wackers, Ardeshir Farshidi, Alan H. Gradman, Arthur Reba, Ruben A. Zito, Steven Wolfson, and Richard E. Fearon, and in Pediatric Cardiology to Drs. Norman S. Talner, Marie J. Browne, William E. Hellenbrand, Charles S. Kleinman, George Lister, and Ruth Whittemore. We also appreciate the efforts of our colleagues and friends in the hospitals affiliated with Yale.

In the first chapter, Dr. William W. L. Glenn reviews the development of cardiac surgery, particularly emphasizing the contributions the Yale faculty has made over the years to the establishment of cardiac surgery. No one can comment better on this than Dr. Glenn, who introduced cardiac surgery to Yale and contributed so many pioneering efforts in the development of the treatment of congenital and acquired heart disease. The Glenn Procedure, a shunt between the superior vena cava and the distal right pulmonary artery, is still used. His many contributions to the field were recognized some years ago by his election to the presidency of the American Heart Association, the first surgeon to be so honored. Dr. Glenn recounts the early days of cardiac surgery before cardiopulmonary bypass, the first open heart procedure using cardiopulmonary bypass by Dr. John Gibbon in 1953, and further developments since. This includes the Yale experience in the early days of 150 consecutive repairs of atrial septal defects without a death.

The development of coronary artery bypass surgery for revascularization of the myocardium has been the major thrust of cardiac surgery in the past decade. Direct bypass grafting of obstructed coronary arteries began in the late 1960's with the work of Johnson, Favalaro and others. The first bypass graft at Yale was carried out by Dr. Hammond in 1969. Dr. Geha and colleagues review the Yale experience beginning at the time our present group came together in New Haven in 1976 until 1979. Eight hundred twenty-five consecutive patients had myocardial revascularization for various anginal syndromes during that period. The indications for operations in this group of patients and the types of procedures and conduits used are reviewed. The operative mortality in this series was 1.8% (9 of 503) in patients with chronic, stable angina pectoris, 3% (9 of 306) in those with unstable angina, and 43.7% (7 of 16) in patients with overt cardiogenic shock. The total operative mortality was therefore 3%, or 25 deaths among 825 patients for the entire group having myocardial revascularization alone. In 297 patients with intractable angina pectoris who did not have a previous history of myocardial infarction, there were only two deaths for a mortality of 0.67%. This is an admirable record and indicates the type of results that should be obtained in such patients today. Actuarial survival studies are provided which indicate survival of 95% of these patients at one year, 93% at three years, and 92% at five years. Comparing these survival rates with the group of subjects matched for race, sex, and age indicates that patients having myocardial revascularization tend to approach the survival rate of "normal" people over a period of five years. These results are significantly better than those of other reports. This indicates that myocardial revascularization can be performed with a low operative

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ARTHUR E. BAUE, M.D., Donald Guthrie Professor of Surgery; Chairman, Department of Surgery, Yale University School of Medicine.

mortality in patients with stable or unstable angina with an excellent long-term survival and a high proportion of patients returning to gainful employment. The operation in our experience does indeed prolong life, at least over the initial five-year period. Yale is one of thirteen national centers presently participating in a multicenter, randomized trial of Class 2 angina patients treated medically or surgically. The results of this study will give us a clearer idea as to the best therapeutic modality in this particular group of patients in which angina is not intractable.

It was as recently as 1961 when the first practical aortic ball-valve prosthesis was introduced, and since then artificial valves have gone through a number of modifications, design changes and trials. The development of aortic valve prostheses is reviewed by Dr. Hammond and colleagues through the various design modifications and clinical trials. In the early days attempts were made to use tissue valves, and they were then discarded in favor of various plastic or metal prostheses. Recently with new methodology in the preservation of valve tissue, the porcine or pig valves have been in more common use. Dr. Hammond reports on the experience of our group at the Yale-New Haven Hospital with 433 porcine prosthetic valves with an overall mortality for aortic valve replacement of 4% and for mitral valve replacement of 8%. In this group of valves used particularly because embolization is minimal, there have been only three small transient emboli for an embolic incidence of less than 1%. This is an excellent experience indicating the superb results which can now be provided for our patients with valvular heart disease, whether it be of the aortic or mitral valve. Although the porcine prosthetic valves have now been used for a number of years, some for as long as eight to nine years, it is still uncertain as to whether they will stand up forever. Our group has recently found that these valves are not satisfactory in children because they tend to break down and fail in a short period of time.

In the early days of cardiac surgery, patients were encountered who either had valvular heart disease or coronary artery disease, but few patients survived long enough to have both problems. In fact, significant disease of both kinds was thought to be incompatible with life until methods of support became good enough for these patients to live long enough to have problems in both areas. We have had experience with a sizable number of patients who have had both significant aortic valve disease and also significant coronary artery occlusive disease. Dr. Laks and the group reviewed the experience at Yale with 64 consecutive patients who underwent aortic valve replacement and myocardial revascularization by coronary artery bypass grafting between 1973 and 1978. By careful attention to preservation of the myocardium which was done originally by coronary artery perfusion and more recently by cardioplegic myocardial protection, the mortality in this group of patients with serious cardiac disease has been 4%. Thus, with adequate myocardial protection, excellent results can be obtained in this group of patients.

One of the most exciting and significant developments in cardiac surgery in recent years has been the study and development of methods to preserve the myocardium during the period that the heart has been stopped during intracardiac repair, whether it be replacement of cardiac valves or myocardial revascularization with coronary artery bypass grafts. It was recognized many years ago that the myocardium did not function as satisfactorily immediately after a cardiac operation as it did beforehand, in spite of an excellent technical operative procedure. We recognized that the myocardium would not tolerate a period of ischemia unless it was protected, and methods were developed, therefore, to protect the myocardium by cooling the muscle and using potassium to stop the heart quickly so that the muscle would be better preserved. By these methods of reducing the metabolic requirements of the heart during the operative procedure and of having a quiet, bloodless field, it has been possible to have a much better functioning myocardium at the conclusion of the operation. For this reason, along with others, there has been a dramatic increase in survival of patients with end-stage heart disease who have required an operation. Although the ideal method of myocardial protection has perhaps not yet been developed, the present methods have produced a quantum leap forward in survival of patients with significant cardiac disease. The period of safe arrest of the heart is now over two hours, and in some circumstances, three hours of total cardiac arrest will be tolerated so long as adequate protection is provided with significant cooling, potassium and with substrate being provided. Efforts at improving our capability in this area are an ongoing part of our experimental laboratory in both the experimental development and clinical evaluation of newer and better methods to improve our capabilities in this important area. This area of study and development is reviewed by Dr. Harold Kay, one of our senior cardiothoracic residents, along with Dr. Laks and the group.

The treatment of congenital heart disease has been greatly improved in recent years, beginning with the pioneering work of Robert Gross, Alfred Blalock, William Glenn and others. The field has now progressed to development of methods to correct lesions which were previously uncorrectable. Total correction of complex cardiac defects in the newborn is now possible under certain circumstances, and many children survive now with successful treatment of their congenital cardiac lesions. Dr. Laks, along with Dr. Stansel and the pediatric cardiologists report their experience herewith in the repair of complex congenital cardiac defects using a valve conduit. A porcine xenograft valve is used in a conduit or beneath a patch and provides a satisfactory means of correcting lesions of the right side of the heart where there is a problem with blood flow either due to pulmonary atresia, pulmonary stenosis, truncus arteriosus or transposition. In 46 patients undergoing these complex repairs, there were four deaths, a mortality of 8.6%, an enviable record in these severe defects. The operative technique used by Dr. Laks and the group is illustrated. This is but one example of the types of repair that can be carried out in such children for a myriad of defects of cardiac development.

The treatment of thoracic aortic aneurysms, both dissecting aneurysms and traumatic disruptions of the aorta, is reviewed by Dr. Stansel. The importance of recognizing the signs of traumatic aortic disruption and referral of the patient to a center for repair are emphasized.

Dr. Geha and colleagues review our experience with the treatment of ventricular aneurysms. When an aneurysm is well defined and not involving the entire left ventricle, resection and repair can be accomplished with acceptable mortality and improvement in the functional capability of the ventricle. The surgical therapy of refractory ventricular arrhythmias is also described.

A major thrust of the cardiac surgical program at Yale is to provide excellent operative treatment for patients with cardiac disease that require such approaches. An equally important and major activity is to constantly improve the state of the art and science of our capabilities and to develop clinical advances. In the operating rooms, intensive care units and research laboratories, the cardiac surgical investigators strive to do better tomorrow than they were able to do today. In this regard, many patients at the present time come to our center for treatment with severe cardiac disease, either valvular or coronary artery disease in which there has been significant previous myocardial impairment. This may have taken place because of prior myocardial infarction, ischemia and fibrosis of the myocardium or because of a prolonged period of valvular stenosis or insufficiency producing a pressure and volume load on the myocardium. Such patients present a challenging problem because the prognosis is poor with end-stage heart disease, and the patients have a marginal existence in spite of maximum medical therapy. In such situations the surgeon may be called upon to attempt to do something, even though the risk is significant and the mortality is high. If there are correctable lesions such as bypassable coronary arteries or valvular heart disease, such patients might be treated successfully if the myocardium can be supported adequately to get through the operation. For such patients Dr. Laks reviews the use of the two methods of support presently available at our institution, intra-aortic balloon counterpulsation and the ventricular assist device helping to pump blood directly from the left ventricle to the aorta in order to wean such patients from cardiopulmonary bypass until the myocardium recovers from the insult. The present status of cardiac transplantation and studies of development of artificial hearts are reviewed.

In summary, during the past decade coronary artery bypass grafting has become established as the best method of treatment for intractable angina pectoris and other complications of coronary artery disease. In patients requiring such operations survival is prolonged, and the grafts remain functional in most patients for many years. The tissue or biologic cardiac valve prosthesis used in the early days of cardiac surgery and discarded was brought back in a newer form and has now become established as the valve of choice for replacement in adults. Total correction of many complex congenital anomalies in the infant was established and improved upon. The development of methods to preserve the myocardium during the necessary ischemic period in open cardiac surgery has greatly improved survival of all patients. Myocardial protection has widened the age range and the extent of disease that can be treated surgically. Needed for the future are even better prosthetic valves, better methods to identify those patients either at risk from sudden death from coronary artery disease or before irreversible cardiac damage has occurred, and advances in immunologic control of rejection so that cardiac transplantation can be practical in adults as well as children with uncorrectable anomalies. We hope that we can continue to contribute to these advances and also continue to provide for our patients in this region cardiac surgical capability of the highest order when it is required.

Some Account of the Early Years of Cardiac Surgery

WILLIAM W. L. GLENN, M.D.

It is the purpose of this paper to give some account of the early years of cardiac surgery; and, because this issue of the Journal is devoted to the cardiac surgical program at Yale, to point up some of the contributions made by Yale cardiac surgeons.

Surgical operations on the human heart began just under 100 years ago when, in 1897, the intrepid surgeon Rehn repaired a lacerated ventricle.[53] The first attempt at operative treatment of heart disease from non-traumatic causes was made in 1913 by Doyen who passed a small knife through the ventricle to relieve pulmonic stenosis.[18] Unfortunately the stenosis in his patient was infundibular and relief was incomplete. Thirty-five years later using essentially the same operative approach, Brock[11] and Sellors[57] established transventricular valvulotomy as effective treatment for pulmonic valvular stenosis. Also in 1913, Tuffier attempted to dilate the stenosed aortic valve by invaginating the wall of the aorta with his finger.[67] The following year, Alexis Carrel, the great experimental surgeon, exposed the aortic valve in an animal after "clamping *en masse* the pedicles of the heart."[13] An exposure of only two or three minutes was possible, hardly time enough to reconstruct a deformed valve, but this was a fair beginning to the modern operative management of lesions involving the aortic root. The first successful clinical intracardiac operation was the digital commissurotomy to relieve mitral stenosis performed in 1925 by Souttar through the left atrial appendage.[63] Though the patient survived and was relieved of symptoms by the operation, Souttar was unfortunately not sent a similar case.

Surgery for Congenital and Acquired Heart Disease

The modern era in cardiac surgery began in 1938 with the successful ligation of a patent ductus by Gross.[29] Sometime later, the cardiac surgical group at Yale were able to report 110 operative closures of the patent ductus arteriosus without mortality, using, in most cases, a suture technique devised by them.[24] Successful operations for other congenital anomalies were soon to follow. In the treatment of cyanotic heart disease two shunting procedures delivered unoxygenated blood directly to the pulmonary artery; one, developed by Blalock and Taussig,[10] consisted of a systemic artery-pulmonary artery anastomosis and the other, developed at Yale,[25] a systemic vein-pulmonary artery anastomosis. Both shunts, or modifications thereof, continue to be employed for certain uncorrectable anomalies of the right side of the heart.

Reconstructive operations for complex intracardiac defects began with the total correction of a tetralogy of Fallot by Lillehei and coworkers in 1956. In their early work these surgeons utilized a living donor as the oxygenator in the extracorporeal circuit.[43] Intra- and extracardiac by-passing of cardiac defects with conduits was pioneered by the Mayo team.[38 46 52]

The matter of surgical correction of deformed cardiac valves which was abandoned in the 1920s was revived in the late 1940s by the work of Smithy,[61] Harken[33] and Bailey.[3] At this time, the attack on the stenosed mitral valve was made with the unguarded finger or with cutting instruments. The failure of the finger to gain a sufficiently wide opening and the production of gross valvular incompetence by the blindly applied valvulotome encouraged the use of metal dilators. In several hundred cases Yale surgeons used a tailor's thimble attached to the index finger to separate the fused commissures more widely.[28] Commissurotomy in the functioning heart continues to be one of the most effective cardiac operations; an operative mortality of one percent or less and symptomatic relief for 10 to 30 years can be expected following a technically satisfactory operation.

Operations for stenotic lesions of the aortic valve were done, as were those on the other cardiac valves, with the heart functioning. Smithy advocated the

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transventricular approach, though he himself a victim of aortic stenosis did not live to see his promising early work fulfilled. This approach was employed by Bailey in patients in 1950.[4] Several years later the group at Yale reported a technique for dilatation of the aortic valve by digit or instrument inserted through a fabric diverticulum sutured to the aortic valve. The diverticulum approach was adopted also for mitral and pulmonary valve operations.[23]

In 1956, utilizing inflow occlusion, as did Carrel in 1914, and total body hypothermia for protection, Lewis and associates[42] and Swan and Kortz[66] were able under direct vision to incise expeditiously aortic valve commissures in patients.

Prosthetic valves came into use in the mid 1950s following Hufnagle's partial control of aortic regurgitation by means of placement of a plastic ball into the descending aorta.[35] Replacement of the aortic valve in the subcoronary position became possible with the advent of cardiopulmonary bypass, and in 1961 Starr adapted the ball valve to this position.[65]

Biologic valves were substituted first in 1956 by Murray[50] who transplanted aortic valve allografts in the descending aorta to treat regurgitation. Ross in 1962 replaced the aortic valve with an allograft sutured in the subcoronary position[54] and Senning in 1967 with a valve fashioned from fascia lata.[59] The early tissue valves were sewn into position without artificial support; the addition of a supporting stint has facilitated their attachment.[19] The porcine xenograft which was first used in 1967[8] has gained increasing popularity. Nevertheless it, like other biologic valves, has been found subject to deterioration. The ideal substitute valve has not been developed, despite the impressive technological advances of the past decade.

Vascular Prostheses

Gross in 1948 replaced a portion of the thoracic aorta with a biologic prosthesis, repairing a long coarcted segment of aorta with an arterial allograft.[30] Controlled hypotension was introduced by the Yale group and by others to facilitate operations on the thoracic aorta.[22] Aneurysm of the thoracic aorta was treated by intrasaccular wiring or wrapping until the mid 1950s when, aided by newly perfected techniques for blood vessel surgery and the availability of cardiopulmonary bypass, Bahnson[2] and DeBakey and associates[16] pioneered, respectively, tangential excision and resection of the dilated segment. The replacement of diseased aortic segments with fabric grafts by Blakemore in 1954 revolutionized the surgical treatment of vascular disease. At first there was no standard graft design or material, and it was not unknown for a surgeon on the night before operation to construct the arterial prosthesis himself from a swatch of cloth taken from a nylon uniform. Nylon when implanted proved not to be durable and was superseded in commercially produced prostheses by dacron or teflon.

Oxygenators

The earliest reference to a true artificial lung dates back to about 100 years ago, to 1882, when von Schröder[68] oxygenated blood extracorporeally by means of a continuous flow device which bubbled oxygen through the blood. It is interesting that Le Gallois[41] in 1813 envisioned indefinite artificial support of the circulation through the continuous perfusion of oxygenated blood, a feat still to be accomplished. A practical pump-oxygenator device to replace the heart and lungs temporarily was designed by Gibbon and used successfully by him in an operation to close an atrial septal defect in a patient in 1953.[21] Some years later the group at Yale reported their total operative experience with this lesion up to that time, 150 operations without a single mortality, thus establishing a bench-mark for open-heart operations using a pump oxygenator with extracorporeal circulation.[64] Deliberate fibrillation of the ventricles, introduced into clinical use by the Yale group to produce a quiet operating field and prevent air embolism during procedures with the heart open undoubtedly contributed to the safety of this and other intracardiac operations.[27]

In the 1950s when various extracorporeal oxygenators were being designed, it was recognized that ideally blood circulating through the extracorporeal circuit should not come in contact with the ambient air. A thin plastic membrane would separate blood from air yet allow diffusion of gases. In 1956 Kolff[39] and Clowes[15] designed membrane lungs similar in principle to Kolff's artificial kidney. Other than those in Cleveland, the Yale surgeons were the only ones to report successfully using this early membrane oxygenator. Yale's contribution to its application to cardiac surgery was demonstrating that ethylene oxide gas, now the standard agent for sterilizing all pump oxygenators, was a safe, effective agent for sterilizing this complex apparatus.[20]

Preservation of the Myocardium During Open-Heart Surgery

In cardiac operations done with cardiopulmonary bypass it is common practice today to arrest the heart to gain ideal operating conditions. It may not be appreciated generally that the present day method, which combines cardioplegic drugs and hypothermia was in vogue over 20 years ago following the work of Melrose,[47] Moulder,[48] Sealy[56] and others. However, the potassium citrate solution employed caused focal necrosis of the myocardium and was abandoned as a cardioplegic drug. Potassium chloride in a balanced solution appears not to damage the heart[31] and, indeed, as reported recently from Yale[7] may, when added to a modified Krebs solution, be the ideal drug for long-term preservation of hearts for transplantation.

Replacement of the Heart

Developing an artificial heart to implant in the body which will function efficiently for an indefinite period has been the dream of cardiac surgeons since the first patient with an uncorrectable intracardiac deformity presented for operation. It is said that Charles A. Lindbergh, the aviator, was stimulated to design an artificial heart by the death of a sister-in-law from rheumatic mitral valve disease. He saw the heart as a simple pump that could be replaced by a mechanical substitute. From 1930 to 1937 the heart pump he designed Lindbergh used in experiments with Carrel on prolonged perfusion of individual organs[44] (Figure 1).

It is interesting that the first significant contribution made by Yale surgeons to cardiac surgery was an artificial heart prototype.[60] Described at the Surgical Forum in 1949, the simple, air-powered, pressure-vacuum pump (now on permanent display at the Smithsonian Institute) was constructed from ordinary laboratory parts and a small motor obtained from an Erector set, all costing less than $25 (Figure 2). Employing this pump in survival experiments, the Yale investigators kept the right atrium or ventricle wide open for up to two hours. Several years later, in 1953, Dodrill applied this concept of right heart bypass to a pulmonary valvulotomy, in what became the first successful open-heart operation aided by a mechanical pump in man,[17] preceding by several months Gibbon's repair of an atrial septal defect which used a bilateral cardiopulmonary bypass.

Designing an implantable pump to take over the function of the entire heart for an indefinite time has proved exceedingly difficult. Akutsu and Kolff, who in 1958 were the first to implant a mechanical total heart in an animal,[1] have some 20 years later reported experiments in calves in which survival following implantation of such a device has been no longer than several months. Two of the difficulties to overcome are fatigue of pumping chamber materials and clot formation at their surfaces. How to power the unit is also still unsolved. The probable solution is energy transmission from the exterior by radiofrequency impulses, which experiments in the Yale surgical laboratories have suggested is feasible.[34] To control inflow and outflow through the mechanical heart, there has been incorporated in the design a feed-back servo mechanism, a device which has been used in patients as an assist pump in cases of left ventricle failure.[40]

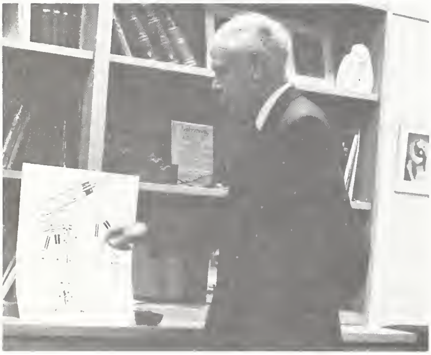

Figure 1
Charles A. Lindbergh, during a visit to the Yale Surgical Laboratory in 1965, demonstrates the action of a pump designed by him and used in Carrel's laboratory for prolonged perfusion of small organs.[44]

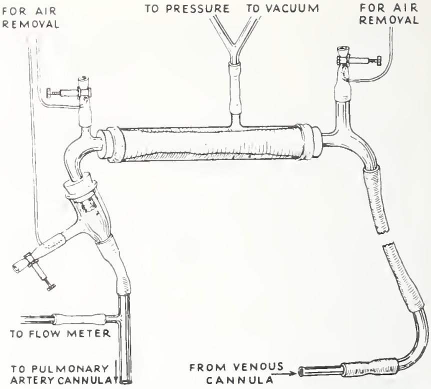

Figure 2
Ventricle type pump designed in the Yale Surgical Laboratory by William H. Sewell, Jr. in 1948-49 when he was a third year medical student, and used in our earliest experiments on cardiac surgery.[60] Both this pump and the one designed by Lindbergh are on permanent display at the Smithsonian Institute.

The first transplantation of a living heart was Carrel's and Guthrie's heterotopic transplantation in a dog in 1905.[12] Lower and Shumway in 1967 reported a technique for orthotopic transplantation in the dog,[45] which is the basic one for the human heart. The first successful heart transplantation in man was that of Barnard and his group in 1967.[5] Today transplantation operations are being done in a few centers highly specialized to obtain optimum results. Postoperative survival of over five years is common now in the Stanford experience.

Revascularization of the Heart

In the surgical treatment of coronary heart disease the pioneering work of Claude Beck deserves special mention.[6] His persistent effort over many years to enhance the failing coronary circulation and his aggressive approach to treatment in myocardial infarction served as foundation stones for present day management.

Many methods of increasing the blood supply to the heart short of direct revascularization were applied to patients with angina pectoris between mid 1930 and mid 1960. The proponents of all methods claimed relief of angina in a high percentage of cases; relief did not persist, however, in most of these. Curiously, direct revascularization of the heart by grafting a systemic artery to a coronary artery, which was shown by Murray in experiments in 1954[49] to be feasible, was not done in humans until the mid 1960s.

A critical factor in the success of direct revascularization has been positive identification by angiography of the site and nature of the occlusive lesion as perfected by Sones;[62] also, perfection of microvascular surgical techniques,[37] with which there had been some experience in revascularization procedures in the lower extremities. The first coronary artery bypass (CABG) at Yale was performed in 1969 and the number of such operations increased rapidly.[32] Controversy still exists over the selection of candidates for CABG, but there is no question about the symptomatic relief the operation brings sufferers of intractable angina. Because of this effect coupled with the low mortality rate (range of 1 or 2%) from operation in uncomplicated cases of angina, the operation enjoys great popularity at present.

Pacemakers

The first account of electrical stimulation applied through the chest of a human, in what was considered a successful resuscitation, was published in 1774 through the Registers of the Royal Humane Society.[55] In 1809 Burns recommended the use of electricity for the treatment of cardiac arrest, but not until 1929 was there successful restoration of the human heart beat by direct electrical stimulation of the myocardium.[36] In 1952 Zoll introduced transthoracic repetitive stimulation via electrodes on the skin.[70] The procedure was poorly tolerated by the patient owing to the discomfort produced by the shock on the chest wall and the skin irritation. Direct epicardial stimulation was introduced in the mid 1950s to treat surgical interruption of the conduction bundle in the course of repairs of congenital heart defect.[69] It was soon evident that prolonging this type of cardiac pacing inevitably lead to infection. To combat this problem and those attending transthoracic pacing, an implantable pacemaker was needed. Such a pacemaker was designed in the Yale surgical laboratories in 1958. It utilized radiowave transmission of impulses from the outside across the intact skin to internally implanted receiver and electrodes. This so-called RF (radiofrequency) pacemaker was used to treat a patient for the first time in 1959 to control repeated, severe Stokes-Adams attacks.[26] Incidentally, this was the first clinical application of long-term stimulation of excitable tissue using transmission of energy across the intact skin to an implanted passive stimulator. About the same time, Senning implanted in a patient a rechargeable battery-powered pulse generator with attached electrodes[58] and in 1960 Chardack reported the non-rechargeable battery-powered unit[14] which soon became the standard pacemaker. The RF pacemaker continues to be used for certain atrial arrhythmias[51] and RF transmission is the common method for stimulation of neural tissue at the present time.

Overview of Cardiac Surgical Operations at Yale

The type and number of cardiac operations performed today are quite different from those done 30 years ago.* The introduction of cardiopulmonary bypass, valve replacement, prosthetic grafts, pacemakers, and CABG has vastly broadened the scope of surgical treatment of heart disease. The total cardiac surgical experience at Yale from 1948 through 1979 is illustrated in Figures 3 through 6.

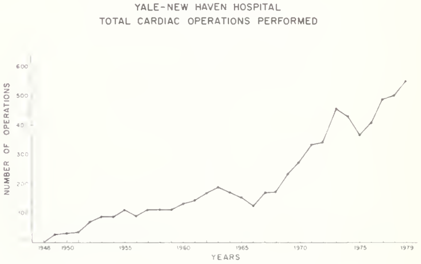

Figure 3

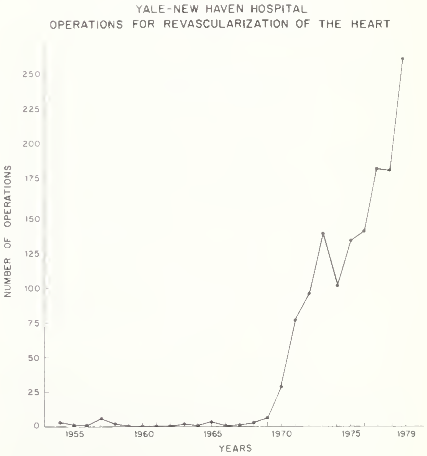

Figure 4

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* This review includes only cases entering the program following the writer's appointment to Yale in 1948. A few extra-cardiac operations for congenital heart disease were done prior to this.

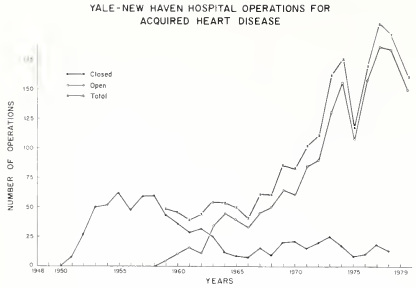

Figure 5

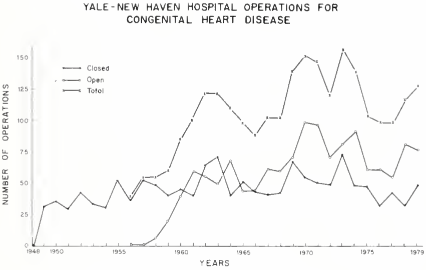

Figure 6

Figure 3 charts the increase in the total number of operations performed on the cardiac surgery service at Yale since 1948. Figure 4 shows the number of CABGs, not done as part of another cardiac operation, to be still rising, and rapidly. Figure 5 shows a rise also in the number of operations for acquired, non-coronary artery disease, a rise partly attributable to inclusion in this category of CABGs done as part of another cardiac operation such as valve replacement or aneurysm resection. Not included here are pacemaker implantations unless primary ones for epicardial electrodes. Figure 6 shows operations for congenital lesions to have been relatively stable over the past decade.

Comment

The surgical treatment for heart disease has made gargantuan strides in the past 30 years, to the point that it can now be said that most cardiac disease is amenable to operation. Unfortunately, operations for heart disease are in many instances not truly curative, since it is the nature of some of the procedures themselves to create abnormal conditions, many of which, in turn, necessitate further replacements or repairs.

From the vantage point of observing the development of cardiac surgery over these 30 years, it is interesting to speculate on what will happen in the next 30. It is obvious that CABGs and pacemaker insertions, which now lead the list of cardiac operations in the United States, will continue to be performed in large numbers for the time being. There are several reasons to expect the former to decline. Elective operations for non-critical disease in cases where medical management will not be life-jeopardizing will probably decrease. Continued referral would depend on its being demonstrated that operation prolongs life, recipients are rehabilitated thereby sufficiently to resume productive employment, grafts remain patent for many years, and there is insignificant placebo effect in cases where grafts close. Further, as is suggested by the recent decline in deaths from heart disease there is probably greater public awareness of and attention to coronary risk factors. If this trend continues it will be a major factor in reducing the volume of required CABG operations.

As for pacemaker battery replacements, they have dropped sharply with the advent of the long-lasting (lithium) battery. The new units, estimated to remain effective as long as 10 years, may outlast many of their host patients whose average age at the time of initial pacemaker implantation is near 70.

Operations for congenital heart disease will probably be less often performed as birth control measures reduce the number of births and defective fetuses. Operations for valvular disease secondary to rheumatic fever will certainly decline in number, and may virtually disappear as rheumatic fever ceases to be a significant clinical problem.

It is apparent from the above that over the next 30 years the rate of cardiac operations as performed today will probably decrease. However, when the present obstacles to cardiac transplantation and cardiac replacement by mechanical substitutes have been removed there will be a new surge of activity in cardiac surgery.

In this brief historical review, because of the constraints of space, I have failed to mention a host of contributors to the development of cardiac surgery. Nor has it been possible to discuss the many contributions of anesthesiologists, cardiologists, radiologists, and technologists which have been critical to the development and success of this new speciality. Suffice it to say that what has been accomplished, at Yale, at least, would have been impossible without a team effort. Nowhere in medicine is there a better example of cross discipline cooperation in the care of patients.

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Myocardial Revascularization for Coronary Artery Occlusive Disease

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ABSTRACT—Early and long-term evaluation of the results of myocardial revascularization shows a hospital mortality of 1.8% (9/503) in patients with chronic stable angina, 3.0% (9/306) in those with unstable angina, and 43.7% (7/16) in patients with cardiogenic shock. Survivors have a 5 year actuarial life expectancy similar to that of the normal population. Ninety-seven percent of the survivors were improved by one functional class or more and 87% were asymptomatic. Eighty-two percent of patients under the age of 60 at the time of operation resumed gainful employment, a substantial increase in comparison with their status 6 months before operation. A multi-center randomized study of patients in whom the indications for surgery or medicinal therapy at present remain equivocal is expected to give us a clearer idea as to the best therapeutic modality in such patients.

Myocardial revascularization by direct grafting of obstructed coronary arteries, developed in the late 1960s by Johnson[1] and Favaloro[2] and their colleagues, has become widely accepted in the surgical manage-

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ment of coronary artery disease, and more than 75,000 of these operations are performed in the United States every year. The procedure offers a direct, logical and rational approach to the problem of myocardial ischemia by augmenting the supply of oxygenated blood available to the area at risk. This report summarizes our experience with myocardial revascularization during a four-year period beginning in 1976, and reviews the current status of coronary artery surgery, including the indications and contraindications for the operation, selection of bypass grafts, the results of the procedure and the outlook for patients after myocardial revascularization.

Clinical Material

During the period January, 1976 to December, 1979, coronary revascularization was performed by the authors in 825 consecutive patients for the surgical treatment of anginal syndromes (Table I). This number represents 49.88% of 1655 patients in whom we had performed open intracardiac procedures during this period of time. The age range was 25 to 82 years, with a mean of 62 years. Table II presents the baseline variables of these 825 patients. Details of preoperative catheterization and evaluation, postoperative follow-up, operative techniques, grafting techniques, and postoperative care have been reported previously.[3 4] Cold chemical cardioplegia, in combination with topical hypothermia, was used for myocardial protection in 405 of the patients, beginning in April, 1977.

Table I

CLINICAL PROFILE: CHARACTERISTICS OF PATIENT SELECTION

	No. of Patients
Total	825 (100%)
Male	586 (71%)
Female	239 (29%)
Angina	825 (100%)
Stable	503 (61%)
Unstable	306 (37%)
Cardiogenic Shock	16 (2%)
Past history of infarction	528 (64%)

Table II

CLINICAL PROFILE: BASELINE VARIABLES

Variable	*No. of Patients*
NYHA classes II & III	454 (55%)
NYHA class IV	371 (45%)
Hypertension	272 (33%)
Congestive Heart Failure	74 (9%)
Diabetes	124 (15%)
Stroke	25 (3%)
Cardiomegaly (C/T > 0.5)	140 (17%)
Hypercholesterolemia > 250mg/100ml	305 (37%)

NYHA = New York Heart Association

During this four-year period, 213 additional patients underwent coronary revascularization combined with other procedures (aortic and/or mitral valve replacement, resection of acutely or chronically infarcted myocardium, closure of septal rupture). These patients are excluded from the review in view of the complexity of additional factors. Combined coronary bypass grafting and aortic valve replacement is reported separately.[5]

The extent of coronary artery occlusive disease is reflected in the number of grafts performed in each patient. Of the 825 patients undergoing isolated myocardial revascularization, 49 (5.9%) had a single graft, 156 (18.9%) had double grafts, and 620 (75.2%) had 3 or more grafts, for a total of 2,711 grafts. Ninety-two patients had one or two internal mammary artery grafts into anterior coronary arteries with or without additional saphenous vein grafts, and 753 had saphenous vein grafts only. Internal mammary arteries were used for bypass grafting in 70 patients during 1976, 15 patients during 1977, 4 patients during 1978 and 3 patients during 1979.

Indications for Operation

The single most common indication for myocardial revascularization is severe incapacitating angina pectoris, intractable to medicinal therapy, in the presence of a hemodynamically significant proximal block of one or more major coronary arteries. Five hundred three patients (61%) underwent elective operation because of this indication. Urgent operation, within 72 hours of catheterization, was performed in 306 patients (37%) because of unstable angina and in 16 (2%) because of cardiogenic shock, Most cardiologists and cardiac surgeons agree that unstable angina constitutes a relatively urgent need for operation since most patients with this syndrome, even when they respond initially to an aggressive medicinal regimen, eventually require surgical intervention.[6] Criteria for the diagnosis of the syndrome of unstable angina and the details of surgical management have been described previously.[7 8] The indication for operation in the presence of cardiogenic shock is a controversial one. We have operated on such patients as a last-ditch effort to salvage a situation which, otherwise, does not show any hope for survival.

High-grade stenosis of the left main coronary artery is probably the most important indication for revascularization and should be considered as urgent. This was encountered in 43 of the 503 patients with stable angina, 82 of the 306 patients with unstable angina, and 3 of the 16 in cardiogenic shock.

Contraindications—Poor left ventricular function with ejection fraction below 0.15 is generally considered as a contraindication for operation, particularly in patients whose predominant symptom is congestive heart failure. The presence of diffuse three-vessel disease and small distal vessels also is a contraindication, since it is usually associated with poor functional and angiographic results even when the operation can be achieved at an acceptable risk. Recent myocardial infarction is also a relative contraindication to operation since it is associated with a substantially high mortality rate, particularly when the infarction is transmural. Operation for continuing angina following a recent subendocardial infarction may become necessary; although the risk is less than with recent transmural infarction, it remains high particularly in elderly patients (Geha, et al: unpublished data).

Selection of Bypass Conduit

The most commonly used bypass graft is the aortocoronary saphenous vein graft (SVG). Early and one year graft patency rates for SVGs have steadily improved over the last 10 years. This appears to be the result of better understanding of the requirements for preservation of the vein, and more meticulous handling of the vein grafts. Currently, SVG patency rates of 95% are achieved two weeks after operation. In a recent report of 110 patients who had one or more SVGs, all of whom were followed up angiographically for 6 years. Grondin, et al.[9] found 92% of all grafts patent at one year and 86% open at 6 years. All of the grafts occluded at 6 years and had significant occlusive lesions at one year, and the disease had progressed significantly in the native circulation in both grafted and nongrafted arteries. This comparatively low dropoff rate of SVGs is very encouraging, particularly in view of the results published by Laks, et al.[10] who sought to determine whether bypass grafting of right coronary arteries with moderately stenotic lesions results in acceleration of the proximal arterial disease and whether the severity of the proximal lesion influences the rate of progress of this disease. They reported that the severity of the proximal lesion did not affect graft patency and did not influence the rate of progression of atheromatous disease in the artery, suggesting that revascularization of less significant lesions may be of value, especially if a high graft patency can be expected.

Our earlier studies[3 11] and those of others[12] a few years ago had shown more encouraging results with the use of the internal mammary artery (IMA) as a bypass conduit than with the SVG. However, the above mentioned improvements in patency of the SVGs and the relative abundance of the sturdier vein grafts have led to a gradual decline in the use of the IMA over the last few years. This is reflected by the frequency of use of IMA grafts in our patient population over the last four years. We currently reserve the use of the IMA for grafting of the left anterior descending coronary artery in the absence of an adequate SVG, in patients with a previously failed SVG to the left anterior descending coronary artery, or in young muscular male patients with stable angina, a very high-grade proximal left anterior descending stenosis, and a large IMA which equals or exceeds the size of the left anterior descending vessel.

Survival Results of Coronary Bypass Surgery

Hospital mortality and peri-infarction rate—The operative (30 day) mortality in each of the three clinical subgroups in this series was 1.8% (9 of 503) in patients with chronic stable angina, 3.0% (9 of 306) in those with unstable angina, and 43.7% (7 of 16) in patients with cardiogenic shock. The total operative mortality was therefore 3.0% (25 deaths among 825 patients) for the entire group with isolated myocardial revascularization. Mortality was increased in patients with generalized ventricular dysfunction and markedly decreased ejection fraction by left ventriculography, and in patients with acute myocardial infarction occurring shortly before or around the time of operation. There were two operative deaths among the 297 patients (0.67%) who did not have a previous history of myocardial infarction. Electrocardiographic and/or enzymatic evidence of myocardial infarction developed in 4% of these patients undergoing myocardial revascularization.

There was no significant difference in mortality rate or perioperative infarction rate regardless of the method of myocardial preservation used. Cold chemical cardioplegia together with systemic and topical hypothermia was used in 405 patients, intermittent aortic cross-clamping with systemic and topical hypothermia was used in 122 patients, and continuous perfusion of the normothermic fibrillated heart with local occlusion of the coronary vessel being grafted was used in 298 patients. However, the high mortality for combined bypass grafting and valve replacement which had been observed several years ago steadily declined during the period of this study, probably as the result of better methods of myocardial protection.[13]

Late Survival—Long-term follow-up for this current series is relatively short. Our analysis of long-term survival in patients undergoing operation prior to the period of this study,[14] however, indicated an actuarial survival of 95% at one year, 93% at 3 years, and 92% at 5 years. This survival was compared with the expected survival of a group of subjects matched for race, sex and age, and the reported survival curves of medically and surgically treated patients with stable angina reported in the Veterans Administration Cooperative Study[15] (Figure 1). These comparisons showed that the longevity of patients with myocardial revascularization tends to approach that of "normal" people over a period of 5 years, and significantly exceeds that reported from the Veterans Administration Cooperative Study. Late survival was also analyzed according to the presence of stable or unstable angina as an indication for operation and with the existence of double or triple vessel disease. The analysis did not show any significant effect of these

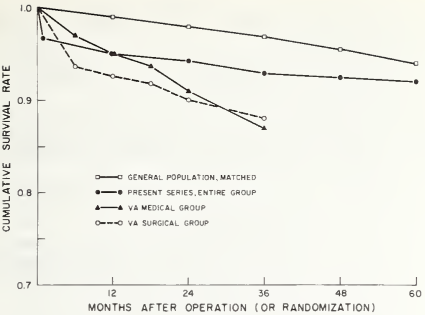

Figure 1

Actuarial survival curve for 547 patients with coronary revascularization undergoing operation in 1972-1976. They include 402 patients with stable angina, 134 with unstable angina and 11 in cardiogenic shock.[14] Survival is compared with expected "normal" survival obtained from life tables for subjects matched by age, sex and race, and with actuarial survival curves reported from the Veterans Administration Cooperative Study[15] of patients with stable angina randomly treated with medical or surgical therapy.

factors on the survival curves of surgically treated patients over a period of 5 years.[14]

Clinical and Functional Results of Coronary Bypass Surgery—In addition to the quantitative effect of coronary bypass surgery, namely its effect on longevity and survival, it is extremely important to ascertain its qualitative results, i.e. its effects on the quality of life of the patients undergoing the procedure. Preoperatively, 12% of the patients were classified in Functional Class II of the New York Heart Association, 43% in Functional Class III, and 45% in Functional Class IV, including all patients with unstable angina and cardiogenic shock. In comparison with their preoperative status, 97% of the survivors were improved by one functional class or more at the time of late follow-up; 87% were asymptomatic at the time of the last follow-up.

We had previously analyzed the socioeconomic impact of the operation in an earlier group of patients.[14] In carrying out such an analysis, it became clear that several financial factors affect the motivation of patients who are close to retirement age. We therefore analyzed the degree of rehabilitation in patients less than 60 years of age. Only 32% of such patients were working up to one month before operation, and 49% had been working within 6 months prior to operation; postoperatively, however, 82% of the patients resumed gainful employment, although some of them took new jobs that were physically less strenuous.

Comments

Analysis of the overall results indicates that myocardial revascularization can be peformed with a low operative mortality in patients with stable or unstable angina and can be expected to provide significant relief of angina. Our results indicate a very high proportion of patients without symptoms at the time of follow-up as well as a high proportion returning to gainful employment.

Our earlier studies also indicate that the operation does indeed prolong life, at least over a 5-year period. We had compared our survival curves with those compiled by the Veterans Administration Cooperative Study for patients with stable angina treated medically or surgically,[15] since their medical series would be anticipated to give the best results of any medically treated group. This is due to the fact that it consists only of patients with stable angina and angiographically documented coronary obstruction, and offers these patients the advantage of current medical therapy for ischemic heart disease, including extensive use of beta blockade with propranolol. In contrast to the data of the Veterans Administration Cooperative Study in which the surgical results were not different from the medical results over a 3-year period, our group, which included patients with unstable angina and a small proportion with cardiogenic shock, showed a significant improvement in survival over 5 years of follow-up.

Controversy continues to exist, however, regarding the effect of coronary revascularization on longevity of patients with stable Class II angina pectoris and those who have recovered from a myocardial infarction and have become asymptomatic. A recent multi-center randomized study of Class II angina patients treated medically or surgically, carried out in Europe, suggests that the survival of these patients is better with surgical treatment when there is triple vessel occlusive disease.[16] In 1976, the Yale University School of Medicine was selected as one of 13 centers in the United States to participate in a randomized trial comparing coronary artery surgery with medical management in patients with Class II angina or patients who have recuperated from a myocardial infarction.[16] It is hoped that the results of this study, when terminated, will give us a clear idea as to the best therapeutic modality in these patients in whom the indications for surgery or medicinal therapy at present remain equivocal.

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Development of Aortic Valve Prostheses

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The development of a practical aortic valve prosthesis in 1961 by Starr, ushered in one of the most dramatic and important periods of development in modern medicine. Our present ability to replace diseased heart valves represents a fascinating and intriguing culmination of the ideas and efforts of engineers, physiologists, surgeons, businessmen and the private enterprise systems in the United States. If the experience and background from any of these areas had been missing, prosthetic heart valves would never have been developed. Even though there were, and still are, problems with the ongoing process of prosthetic heart valve evolution, in the past 20 years it has reduced the 18 month mortality rate of symptomatic aortic stenosis from 50% to 5%.[1]

The original Starr-Edwards aortic valve prosthesis (Figure 1) consisted of a stainless steel cage, Silastic ball and Teflon sewing ring. The stainless steel comprising the struts extended into the orifice of the valve

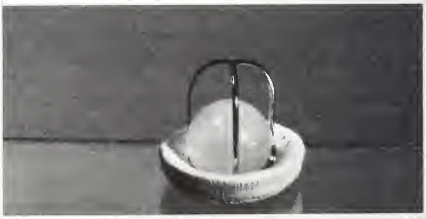

Figure 1
Original Starr-Edwards aortic valve prosthesis with stainless steel struts, Silastic ball and dacron sewing ring.

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so that the ball seated against steel. (Figure 2). Blood, as it egressed from the left ventricular chamber, made contact with this steel ring. Although these valves were effective in relieving the gradient of aortic stenosis or the regurgitation from insufficiency, they had two serious drawbacks. First, blood tended to clot at the apex of the struts and at the point where the struts join the stainless steel outflow orifice. This resulted in a thromboembolic rate of 25 to 35%.[2 3] Second, the Silastic balls had a tendency to absorb lipid from the blood and either swell, or crack or both.[4 5] An example of this problem is demonstrated in Figure 3. This patient underwent aortic valve replacement at the Yale New Haven Hospital in the mid 60s. She did well for several years until being readmitted in moribund condition. She died shortly afterward and postmortem examination revealed the fractured ball. Figure 4 shows a ball two years following implantation of the valve in comparison with a normal ball; the distortion is obvious. Figure 5 shows a valve removed from a twenty-two year old patient who had undergone aortic valve replacement several years earlier. He was also readmitted to the Yale-New Haven Hospital in moribund condition with no audible heart sounds. He was brought immediately to the operating room, placed on cardiopulmonary bypass and the valve excised. As can be seen, the swollen ball had jammed in the open position. This patient underwent re-replacement with a newer type Starr-Edwards aortic valve prosthesis and has been doing well for the last eight years. A partial solution to this problem was affected by impregnating the Silastic ball with barium so that it could be visualized on chest x-ray. If any early distortion was seen, replacement of the ball could be considered before the occurrence of devastating complications. This modification, of course, did nothing to eliminate the original problem.

Regarding valve clotting and emboli, an interesting observation was made at postmortem examination of patients with prosthetic valves who died six months or more after valve replacement. An example of this can be seen in Figure 3. One will notice that the sewing ring of the valve has been reendothelialized and is covered by the same smooth, glistening endothelium that comprises the wall of the aorta. It was noted that, while clot was often seen on the stainless steel portions of the valve, it was almost never seen on the reendothelialized sewing ring. Accordingly, the next modification of the Starr-Edwards valve was directed towards eliminating the problem of ball variance and thromboembolism.

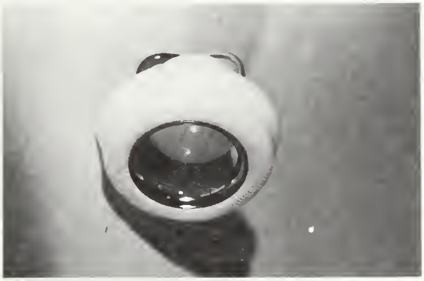

Figure 2
Under surface of original Starr-Edwards aortic valve prosthesis showing stainless steel outflow orifice.

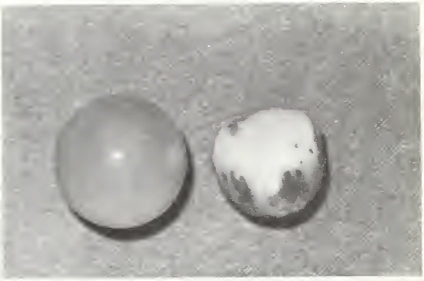

Figure 4
A normal Silastic ball is at the left and a lopsided ball due to lipid absorption is seen on the right.

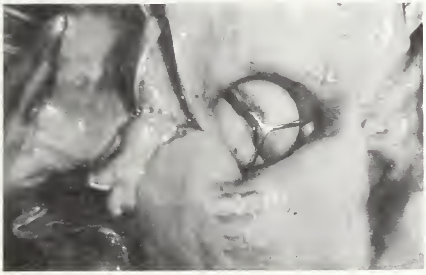

Figure 3
The Silastic ball has been fractured several years after implantation due to lipid absorption and weakening.

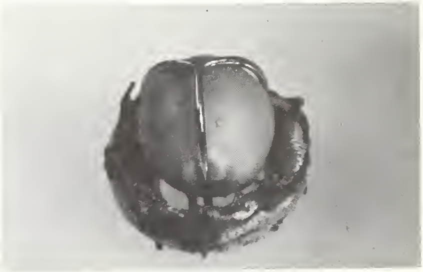

Figure 5
Lipid absorption caused swelling of the Silastic ball which is jammed in the open position.

The newly designed valve was introduced in 1968 and is shown in Figure 6. The Silastic ball was replaced with a hollow metal ball composed of stellite and the valve, except for the ball, was entirely enclosed in woven dacron. Figure 7 shows how the previously exposed outflow tract was also covered with dacron. The rationale for covering the valves was that endothelialized growth would occur over the entire valve as it had on the sewing ring of the previous valve, and hopefully, reduce the incidence of clot formation and thromboembolism. Happily, with this new design, ball variance problems were ended and the embolic rate fell from 25% to approximately 10%, but the patients still required anticoagulation.[6] Unfortunately, anticoagulants themselves were associated with an 8% complication rate.[6]

As the story unfolded, however, serious complications with this valve were soon to be seen. Tissue ingrowth which indeed covered the struts and outflow tract caused its own set of problems. As incorporation of fibrous tissue into the struts occurred, the struts became thicker and encroached on ball movement. In some cases, the ball became frozen in much the same way that the old Silastic ball became frozen after swelling. In addition, in these metal and plastic valves, there was no cellular mechanism to stop the growth of fibrous tissue once the valve was encapsulated. The problem was that fibrous growth across the orifice began to occur producing severe aortic stenosis. Therefore, the valve was redesigned, as seen in Figure 8, to avoid these problems. The struts were widened thereby providing more leeway for ball clearance and small metallic projections were put in the valve orifice where the ball seated. This produced a hammer and anvil effect. When a fiberblast grew onto the metal projections the ball would come down and stamp it out. Accordingly, fibrous growth across the valve orifice was continuously trimmed back.

This valve too, had its problems. The ball impinging on the struts tended to wear away the cloth and the sharp, exposed spicules of dacron caused severe hemolysis as the red blood cells sheared past. The incidence of hemolysis from this cause was approximately 5%.[7] Figure 9 shows a valve which we removed in our series for severe hemolysis. The fabric had become completely unwrapped from the strut. This problem was corrected in the final modification of the Starr-Edwards prosthesis which is shown in Figure 10. A track was incorporated on the inner aspect of the struts protecting the dacron from the ball.

An inherent problem in all ball valves is tertiary orifice obstruction. No matter what subtle modifica-

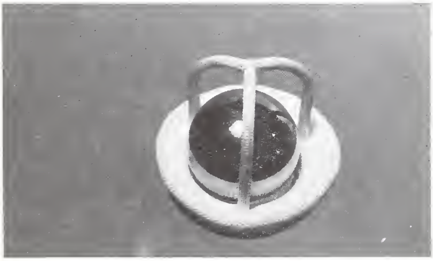

Figure 6
Newer type Starr-Edwards aortic valve prosthesis with stellite ball and dacron covered struts.

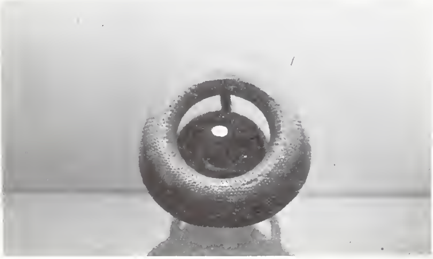

Figure 7
Outflow tract of the newer type valve shows covering of the outflow orifice with dacron.

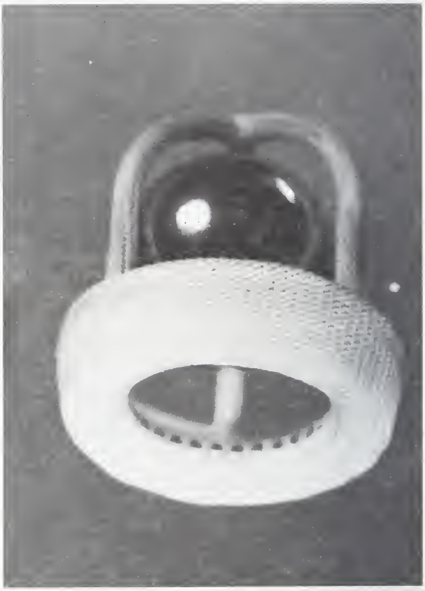

Figure 8
A later development in the Starr-Edwards valve shows the metal studs in the outflow orifice which are impacted by the ball thereby reducing tissue overgrowth across the outflow orifice.

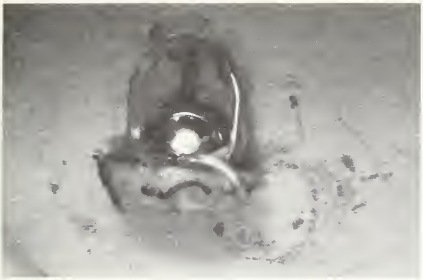

Figure 9
This cloth covered Starr-Edwards valve was removed a year after implantation due to hemolysis secondary to cloth wear.

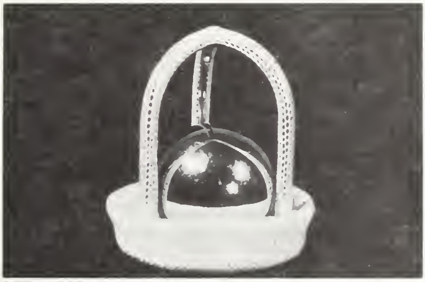

Figure 10
Latest model Starr-Edwards aortic valve showing stainless steel tracks on the inner side of the dacron covered struts.

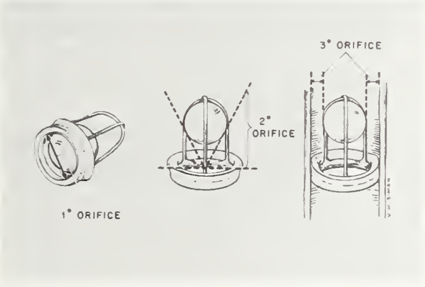

Figure 11
Three orifices produced by ball valves.

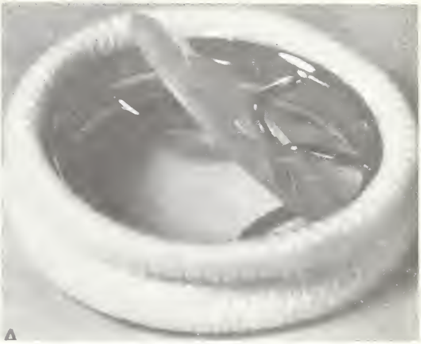

Figure 12
Bjork-Shiley Valve.

tions are made in valve design, the ball valve will always be plagued with this problem. These valves have three orifices. As shown in Figure 11, the primary orifice is the orifice through which the blood must go when leaving the left ventricle. The secondary orifice is the orifice subtended by the angle made from the ball in the open position and the primary orifice. The height of the cage determines the size of the secondary orifice and obviously, in proper valve design, the primary and secondary orifices are equal. The tertiary orifice is the orifice between the perimeter of the ball in the open position and the walls of the aorta. It is this orifice that cannot be controlled by design of the valve and which can cause severe obstruction to blood flow. The ball valve, therefore, creates a paradoxical problem. If one wishes to insert a valve with a large primary orifice one will then create a small tertiary orifice due to the size of the ball. This problem was beautifully documented by Lillehei's group[8] in 1968. To obviate the problems of tertiary orifice obstruction, a number of different valve designs have appeared in the last ten years. Most notable is the Bjork-Shiley valve pictured in Figure 12. The ball has been replaced by a disc shaped poppet which when open, causes very little obstruction to blood flow. Unfortunately, the disc valves too have their own inherent problems; specifically poppet sticking and thromboembolism. Shown in Figure 13 is a thrombosed Bjork-Shiley valve from one of our own patients.

The newest valves and those which are in widest clinical use today, one of which is shown in Figure 14, are the porcine valves. These are manufactured by Edwards and Hancock Laboratories in Santa Ana, California. In the period from 1976-1979, our group at the Yale New Haven Hospital inserted 433 porcine prosthetic valves. For all categories of patients the overall mortality for aortic valve replacement was 4% and for mitral valve replacement, 8%. There have been only three small transient emboli for an embolic incidence of less than 1%. The only anticoagulant used was aspirin, and this for only the first six weeks postoperatively. In adult patients we have seen only one problem with leaflet disruption although in children, the incidence has been somewhat higher.[9] The reason for this is not clear although it may involve the

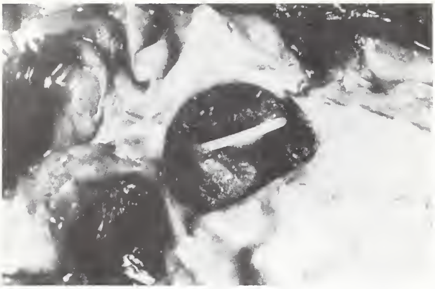

Figure 13
Postmortem examination showing a clotted Bjork-Shiley Valve.

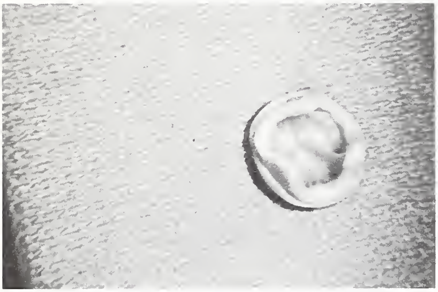

Figure 14
Porcine aortic valve prosthesis.

effect of growth hormone working on the leaflet tissue or a disproportion in valve-patient size as the patient grows.

The long-term outlook for porcine prosthetic valve is not clear. Electronmicroscopy shows minute cracks appearing in the collagen at one year after implantation. However, this appears to have no clinical significance for the present. There have been no problems with hemolysis or tissue ingrowth causing dysfunction. Currently, the porcine valve is the most widely used valve at the Yale New Haven Medical Center and is clearly the valve of choice when there is any contraindication to anticoagulants. However, the history of prosthetic valve design has been one of constant change. These changes have been required due to the occurrence of unforeseen problems. Although many of the most serious problems have been partially corrected or even eliminated, it would be unrealistic to expect that the porcine valve is the final answer to patients with valvular heart disease.

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Combined Aortic Valve Replacement and Myocardial Revascularization

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ABSTRACT—To determine the results for combined aortic valve replacement and coronary revascularization, we analyzed the records of 64 consecutive patients who underwent the combined procedure between 1973 and 1978. Forty (77%) had angina and 40 (77%) were in New York Heart Association Functional Class III or IV. Moderate to severe left ventricular impairment was present in 59%, and the mean number of diseased vessels was 1.9 per patient. Group I consisted of 19 patients in whom coronary perfusion was used, and Group II consisted of 33 patients in whom cardioplegic myocardial protection was used. There were no deaths in Group I and two deaths in Group II, for a combined early mortality of 4%. The incidence of perioperative myocardial infarction was 11% in Group I and zero in Group II. The incidence of cardiogenic shock requiring prolonged inotropic support and intraaortic balloon counterpulsation was significantly less in Group II (9%) than in Group I (49%) ($p < 0.05$). If other manifestations of myocardial injury, such as perioperative infarction and cardiogenic shock, requiring intraaortic balloon counterpulsation or inotropic support, are taken into consideration, cold chemical cardioplegia appears to provide better myocardial protection than coronary perfusion of the fibrillating heart. With adequate myocardial protection, excellent results can be obtained in this group of patients.

Introduction

In order to avoid perioperative myocardial infarction and improve the long term results of aortic valve replacement (AVR) in the presence of major coronary artery disease[1 2] many centers now advocate combined valve replacement and coronary revascularization, even in the absence of angina.[1 3 4 5 6 7] The presence of left ventricular hypertrophy[8] and coronary stenosis[9] in these patients presents special problems in achieving optimal myocardial protection. Several effective methods of myocardial protection have evolved. They include perfusion of the fibrillating heart, topical hypothermia, and cold chemical cardioplegia. Because of the extended nature of the combined procedure, the adequacy of myocardial protection is more critical than for either isolated AVR or coronary revascularization alone.

Having adopted improved methods of myocardial protection we reviewed our experience with 40 patients undergoing combined AVR and coronary artery bypass grafting (CABG).

Materials and Methods

Fifty-two consecutive patients underwent AVR and coronary revascularization at Yale New Haven Hospital from January 1977 to December 1979. There were 45 men (87%) and 7 women (13%). The mean age was 60 years (range 41 to 74 years).

The patients were classified symptomatically, using the New York Heart Association Functional Classification, according to the predominant complaint restricting their activity. Twelve patients (23%) had no

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angina, and for them, the classification for cardiac failure was used. In the remaining 40 patients, the restricting symptom, either pain or dyspnea, was used. There was 1 patient (2%) in Class I, 9 (22%) in Class II, 18 (45%) in Class III, and 12 (32%) in Class IV.

Cardiac catheterization was performed in all patients and included coronary angiography performed in two projections. Lesions decreasing the luminal diameter by more than 70% were considered significant. The mean number of significantly obstructed vessels was 1.9. Left ventricular dysfunction was classified as mild, moderate, or severe on the basis of the angiographic ejection fraction (EF), segmental dyskinesia, and left ventricular end-diastolic pressure (LVEDP). An EF of more than 50% and an LVEDP of less than 10 mm Hg with segmental dyskinesia was considered mild impairment. In the moderately impaired group, the EF was less than 30% and the LVEDP, greater than 20 mm Hg. There were 22 patients (42%) with mild impairment, 26 (51%) with moderate impairment and 4 (7%) with severe impairment. Predominant aortic stenosis was found in 31 patients (60%) and regurgitation in 9 (17%) while 12 (23%) had combined lesions.

Methods of Myocardial Protection

The patients were divided into two groups according to the method of myocardial protection used. Group I consisted of 19 patients operated on between January 1977 and December 1979, in whom systemic hypothermia from 25° to 28°C was utilized with coronary perfusion of the fibrillating heart throughout. Group II consisted of 33 patients operated on during the same time period, in whom systemic hypothermia to 25°C was used, and both the AVR and distal coronary anastomoses were performed using a single cross clamp period. The cardioplegic solution was either cold blood with potassium (30 mEq/L) Ringer's lactate with potassium (30 mEq/L), glucose, and insulin. All solutions were cooled to 4°C prior to administration. Topical hypothermia using cold saline solution (4°C) was usually combined with the cardioplegia. The cross clamp time was a mean of 19 ± 8 minutes in Group I. In Group II, the cross clamp was 103 ± 18 minutes, with the cardioplegic solution administered every 20 to 30 minutes either into the root of the aorta, or into the coronary ostia. The duration of cardiopulmonary bypass was a mean of 159 ± 21 minutes in Group I, and 151 ± 13 minutes in Group II.

The mean age in Group I was 60 ± 7 years; and in Group II, 60 ± 6 years. The Functional Class was a mean of 3 in all groups. These and the other clinical variables such as left ventricular function were not significantly different in the two groups ($p > 0.1$, chi-square test).

Surgical Procedures

The mean number of grafts performed was 1.6 and was not significantly different in the groups (chi-square test). Reverse saphenous vein grafts were used in 38 patients and internal mammary artery grafts in 2. Twenty-one patients (40%) received a Bjork-Shiley valve, and 31 (60%) a porcine heterograft valve. In addition to AVR and CABG 1 patient underwent mitral valve replacement, 1 had mitral and tricuspid valve replacement, 1 had a mitral commissurotomy, and two had mitral annuloplasty.

Postoperative Management

In intraaortic balloon counterpulsation device (IABP) has been in use by our group since 1973. In 6 patients (12%) IABP was used to wean the patient from cardiopulmonary bypass after failure of inotropic agents. In patients who did not require IABP, inotropic agents were required for more than 12 hours to maintain an adequate cardiac output.

Perioperative myocardial infarction was diagnosed from the electrocardiogram because complete enzyme data were available for only the recent patients. A definite infarct was diagnosed by the appearance of new Q waves (> 3 mm in depth, > 0.04 seconds in duration) or by elevation of S-T segments (> 1 mm) for more than 72 hours.

Anticoagulation was begun in the immediate postoperative period for all patients with Bjork-Shiley valves. Patients receiving porcine valves were placed on a regimen of aspirin and Persantine (dipyridamole).

Follow-up was accomplished by clinic visits or reports from referring physicians. The mean follow-up was 22 ± 7 months for Group I, and 9 ± 3 months for Group II.

Results

Mortality

There were no deaths in Group I and two early deaths in Group II (6%) with a mortality in the combined series of 4%.

Postoperative Low Cardiac Output

In Group I there were 3 patients who required IABP, all of whom survived. In Group II, 3 patients required IABP, and two survived. Some patients did not require IABP to be weaned from cardiopulmonary bypass but did not need inotropic support, which had to be continued for more than 12 hours after operation. There were 6 patients (33%) in Group I, all of whom survived, and one in Group II.

Perioperative Myocardial Infarction

Definite myocardial infarction by electrocardiographic criteria occurred in 2 patients (11%) in Group I, who survived, and none in Group II.

Late Deaths

There was 1 late death in Group I (mean follow-up, 10 months), and one in Group II (mean follow-up 9 months). The late deaths were in patients with poor left ventricular function.

Comment

Experimental studies of myocardial protection have shown that perfusion of the fibrillating heart in the presence of left ventricular hypertrophy[8] or coronary artery stenosis[9] results in inadequate preservation. Because coronary stenoses and left ventricular hypertrophy are present in patients with combined aortic valve disease and coronary artery disease it would be expected that problems might arise from the use of coronary perfusion of the fibrillating heart in these patients. It has been shown experimentally[10] that topical hypothermia with ischemic arrest provides incomplete protection for 1 hour of aortic cross clamping and is inferior to cold chemical cardioplegia. The hypertrophied heart also takes longer to cool using topical hypothermia alone.[11,12] One of the advantages of cold chemical cardioplegia is the rapid cooling of the myocardium, which is achieved by perfusion with the solution at a temperature of 4°C. Brazier and associates[13] showed that noncoronary collaterals are better developed in the hypertrophied and the chronically ischemic heart. This could result in more rapid rewarming during the period of ischemic arrest. The combined procedure of AVR and coronary revascularization is thus a more critical test of the method of myocardial protection than coronary revascularization or AVR alone.

Clinical reports have shown that several forms of myocardial protection will provide an acceptably low operative mortality.[7,11,14,15] Of the 18 patients in our series who had perfusion of the fibrillating heart and were operated on during 1977 and 1978, all survived. Others have also reported a low mortality using this technique. Macmanus and associates[14] reported a mortality of 6.3% among 80 patients. Their mortality was not significantly different from the 9% reported by Loop and associates[7] who used ischemic arrest without coronary perfusion for the valve replacement and perfusion of the fibrillating heart for the coronary grafts. This mortality of 9% was, however, three times that of isolated AVR in their situation.

Others have reported on the use of topical hypothermia and ischemic arrest. Pupello and co-workers[11] had no deaths among 36 patients. Richardson and associates[15] reported on a large series of 220 patients and used either coronary perfusion, topical hypothermia, and ischemic arrest or cold chemical cardioplegia. The overall mortality was 5.4% which was not broken down according to the method of protection used. In our series a comparison of the patients operated on with perfusion of the fibrillating heart and those who had cold chemical cardioplegia during the same period (1977 and 1978) showed no deaths in either group. Our experience confirms that with adequate myocardial protection, the mortality of the combined procedure should be no higher than that of isolated AVR.[11,14,15] This would encourage routine coronary angiography and use of the combined procedure even in the absence of angina, which has been so debated in the past.[1-7,14,16-18]

Inadequate myocardial protection is manifested not only by mortality, but by the incidence of perioperative myocardial infarction and the presence of cardiogenic shock requiring either IABP or prolonged inotropic support.

In our series, a perioperative myocardial infarct was diagnosed by electrocardiographic criteria only because enzyme data were not available for all patients. In the group with cardioplegia there were no infarcts, as opposed to 2 in the group with coronary perfusion. There was significantly lower incidence of myocardial infarction in Group II, who had no infarcts, than in Group I ($p < 0.05$), while there was no difference when Group III was compared with Group IIa or Group IIb. Richardson and associates[15] also showed a zero incidence of perioperative myocardial infarction in the cardioplegia-treated patients, and they reported a significantly higher incidence in the groups treated with intermittent coronary perfusion or topical hypothermia and ischemic arrest.

There was also a difference in the incidence of cardiogenic shock requiring treatment in the three groups (Figure 1). In Group I, 17% of the patients required IABP in an attempt to wean them from cardiopulmonary bypass versus 9% in Group II. There

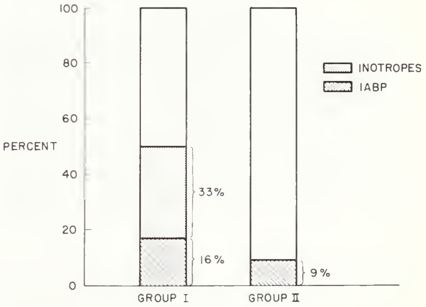

Figure 1
The incidence of cardiogenic shock requiring either inotropes or intraaortic balloon counterpulsation postoperatively is shown. There is a significant reduction in support required in Group II (cardioplegia used) compared to Group I (coronary perfusion).

was also a statistically significant difference ($p < 0.05$) in the proportion of patients who required inotropic support for more than 12 hours: 33% in Group I, and none in Group II. In comparing these two groups, it is apparent that the sequelae of inadequate protection are less common in the group treated with cold chemical cardioplegia.

This study suffers from the deficiencies of most nonrandomized clinical reports, namely, that different surgeons have used different techniques on different patients at different times. Some of these criticisms can be allayed. As described, the patient populations in the two groups were similar and the time factor can be eliminated as Group I and II underwent operation during the same time interval. The methods of postoperative care and the criteria for the use of the intraaortic balloon and inotropes have been similar at any one time regardless of the method of protection employed. Since the incidence of graft patency and perivalvular leak is similar among the surgeons involved, we think that the difference in results can be attributed to the method of protection used.

This study thus shows that myocardial protection affects the results obtained from combined AVR and CABG. Although an acceptably low mortality can be achieved with both coronary perfusion and cold chemical cardioplegia if other manifestations of myocardial injury are considered, such as the incidence of perioperative myocardial infarction and cardiogenic shock requiring either IABP or inotropic support, cardioplegia appears to provide more complete myocardial protection. This low mortality and morbidity support continued use of the combined procedure in patients with aortic valve and coronary artery disease, even in the absence of angina.

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New Methods of Myocardial Protection for Cardiac Surgery

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ABSTRACT—Improvements in the use of cardiopulmonary bypass and in the technical aspects of cardiac surgery resulted in a dramatic increase in operative survival. Recently, further advances have been made in the prevention of myocardial injury during the course of cardiac surgery. As the importance of preventing the depletion of high energy substrates was recognized, attention was directed at reducing the metabolic requirements of the heart or improving its supply. Various methods of myocardial protection have been employed, including perfusion of the fibrillating or beating heart, ischemic arrest with topical hypothermia and most recently, cold chemical cardioplegia. The latter has the advantage of providing a quiet, bloodless field, and in addition, has been shown to provide optimal protection when repeated intermittently. The use of cold chemical cardioplegia has been associated with improved results in cardiac surgery and has reduced the operative mortality, perioperative infarction rate and incidence of cardiogenic shock, especially in complex procedures and in patients with impaired ventricular function.

Introduction

Introduction of the "heart lung machine" by Gibbon in 1954[1] started a new era in the operative treatment of cardiac disease. This discovery enabled the cardiac surgeon to delegate the function of the heart and lungs to the extracorporeal pump oxygenator while performing intricate repairs of cardiac lesions.

Although early results using cardiopulmonary bypass (CPB) were promising, the mortality remained relatively high and it soon became apparent that serious damage was being done to the myocardium while the patient was on CPB.[2 3] It was only after gaining a thorough understanding of the principles of myocardial blood flow and energy utilization that these complications could be prevented. New techniques were devised to prevent loss of ventricular function while on CPB. These methods have come to be known as myocardial protection.

Kinetics of Myocardial Energy Supply and Demand

Normally the myocardium derives energy by metabolizing glucose to CO_2 and H_2O. This highly efficient glycolytic process uses the Embden-Meyerhoff pathway, the Krebs cycle, and the electron transport system to convert one mole of glucose into H_2O, CO_2, and 35 moles of adenosine triphosphate (ATP). The availability of oxygen is the rate limiting step because it is a required substrate for the Krebs cycle and the electron transport system. Without oxygen, the myocyte is forced to use a less efficient anaerobic pathway which produces only 2 moles of ATP per mole of glucose.

Maintenance of high energy stores is critical to the myocardium because even in a "resting state" there are 3 obligatory drains on energy stores:[4-7]

i) ventricular contraction - both isotonic and isometric, which requires the most energy.
ii) basic metabolism - including nuclear protein synthesis.
iii) maintenance of Na^+, K^+, and Ca^{2+} transmembrane ionic gradients.

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The total energy requirements is usually expressed as myocardial oxygen consumption (MVO_2). The subendocardium is the metabolically most active area of the myocardium with the highest utilization of ATP, yet, because blood supply to the subendocardial layer is provided only by branches of the epicardial coronary arteries and because these branches must traverse the full thickness of the myocardium, subendocardial flow is most vulnerable to changes which decrease coronary blood flow or increase its demands. Factors which cause a relative decrease in coronary blood flow include tachycardia, hypertrophy, hypotension, coronary artery disease, inotropic agents, fibrillation, and left ventricular distension. Tachycardia decreases coronary flow by reducing the duration of diastole and thus the time during which myocardial perfusion occurs. Left ventricular hypertrophy decreases coronary blood flow to the subendocardium by increasing resistance to coronary ostia and stenotic vessels of coronary artery disease create an increased resistance to flow. Inotropes increase wall tension, decreasing subendocardial perfusion and usually produce tachycardia. Ventricular distension increases intramyocardial pressure reducing subendocardial flow.

Factors which increase myocardial oxygen demands include tachycardia, hypertension, hypertrophy, and inotropic agents, which increase myocardial work by raising the rate or force of contraction, increasing afterload or increasing the mass of myocardium to be perfused. The rate-pressure product (heart rate X mean aortic pressure) is a frequently used index of myocardial work, and rate-pressure products in excess of 14,000 may be associated with ischemia,[8 9] in the presence of additional factors which restrict flow such as coronary artery disease.

Since most patients who undergo cardiac surgery have one or several of these factors, the potential for a supply-demand imbalance exists. Furthermore, while the normal heart can compensate for this supply-demand imbalance by coronary vasodilation, diseased hearts are unable to vasodilate because of obstructed coronary arteries, or are already maximally dilated and have no coronary reserve. A vicious cycle is therefore created, where decreased coronary flow creates myocardial ischemia, which decreases contractility. This results in an elevated end diastolic pressure, tachycardia and hypotension which further reduce coronary perfusion.

On the cellular level, the loss of myocardial ATP is manifested by an inability of the myocyte to maintain the Na^+ pump, thus allowing intracellular edema.[10 11] There is also loss of capillary endothelial integrity with endothelial swelling, bleb formation and occasional endothelial cell rupture.[12-14] These lesions lead to increased myocardial edema, impaired ventricular function, decreased perfusion, more ischemia and progressive loss of myocyte function until there is frank cell death.

Methods of Myocardial Protection

In order to prevent this vicious cycle of myocardial injury, various methods of protecting the myocardium have been devised, aimed at reducing the myocardial oxygen demands.

Cardiopulmonary bypass is very effective in decreasing myocardial oxygen consumption in several ways:

i) Draining the venous return from the vena cavae or right atrium, drastically reduces the volume work of the heart.

i) Decompressing the ventricular cavity by a left ventricular vent decreases wall tension and increases subendocardial flow.

iii) Lowering myocardial temperature by decreasing the temperature of the blood perfusing the heart reduces myocardial metabolism.

Even on CPB, however, the three basic drains on myocardial energy reserves, namely contraction, basic metabolism and maintenance of transmembrane ionic gradients require an MVO_2 of approximately 6 ml/100 gm/min (Table 1). In addition, it may be technically difficult to perform certain delicate procedures on the beating perfused heart. For this reason additional techniques were developed.

There are three techniques of myocardial protection currently in use: Continuous coronary perfusion, intermittent ischemic arrest, and chemical cardioplegia. These techniques are often combined with systemic and topical hypothermia.

Table 1

The myocardial oxygen extraction (MVO_2) expressed in ml/100 gm/min is shown under different conditions.[32]

Temperature	37°C	32°C	28°C	22°C
Human				
Working Heart	8-14			
Canine				
Beating Empty Heart	5.6	4.9	3.9	2.9
Fibrillating Heart	6.5	3.8	2.9	2.0
Arrested Heart	1.1	.8	.6	.3

I. Coronary Perfusion

Because femoral cannulation was associated with numerous problems including dissection of the aorta and limb ischemia, we currently cannulate the ascending aorta for most procedures. With cannulation of the ascending aorta, systemic flow is antegrade to the arch vessels and the rest of the body, and retrograde through the ascending aorta to the coronary arteries. In cases where the aorta must be opened, e.g. aortic valve replacement, an occluding clamp is placed on the ascending aorta proximal to the arterial perfusion cannula; the aorta is opened and separate perfusion cannulae are placed into the coronary ostia. The major advantage of this form of myocardial protection is that there is continuous flow to the coronary arteries. In addition, cooling the perfusing blood decreases myocardial temperature and MVO_2 (Table 1).

The disadvantages of continuous perfusion can be divided into technical and metabolic problems. Technically, the biggest problem is that the heart continues to beat during perfusion, making it difficult to do delicate operations. The alternative of fibrillating the heart, may result in reduced subendocardial flow, particularly in the presence of hypertrophy or coronary artery disease.[4 15] The use of indwelling coronary cannulae is also awkward, as they are easily dislodged and may result in coronary ostial damage.[16-18]

Metabolically, continuous perfusion still requires a relatively high MVO_2 which, if not supplied, results in ischemia. Hypothermic perfusion has the advantage of decreasing MVO_2 and therefore more closely aligning supply and demand, but cooling below 32°C, usually causes ventricular fibrillation with its attendant problems of reduced subendocardial flow. Because of both technical and metabolic problems, the technique of continuous coronary perfusion is now less frequently used for myocardial protection.

II. Ischemic Arrest

Primarily because of the technical difficulties in working on a vigorously beating heart, the concept of ischemic arrest became popular in the late 1960s and early 1970s. There are two techniques of ischemic arrest, intermittent or continuous, and it has been used with or without topical hypothermia. Using the continuous technique, the heart is cooled to 25°C and a clamp is placed on the ascending aorta proximal cannula. As the data in Table 1 suggest, decreasing septal temperatures to 22°C prolongs the safe ischemic time by decreasing myocardial oxygen requirements. At 22-25°C the heart usually tolerates an ischemic period of 45 minutes. The ischemic time can be prolonged by applying ice to the surface of the heart (topical hypothermia) and decreasing septal temperatures to 11-15°C.[19 20] The operation is completed during one period of ischemia followed by reperfusion and rewarming.

The alternative technique of intermittent arrest and reperfusion has also been used. In this technique the blood is cooled, an aortic clamp is applied for 20 minutes and then the clamp is removed for 5 minutes, or more, to allow for reperfusion and replenishment of the oxygen debt. These periods of ischemia and reperfusion are repeated until completion of the procedure.

The advantage of ischemic arrest is primarily technical. The operation is done in a quiet, bloodless field. There is little or no ventricular distension which means that the heart can be retracted easily.

The disadvantages of ischemic arrest are considerable. After cross clamping, the heart fibrillates until arrest occurs, due to depletion of high energy substrates. Despite the fact that myocardial oxygen consumption is reduced by hypothermia, ventricular fibrillation is an energy-consuming process which requires oxygen as a substrate to produce ATP. In addition, the hypertrophied heart is slow to cool with topical hypothermia.[21] Performing surgery with ischemic arrest and hypothermia sets a limit on the "safe" ischemic time. Complex procedures such as combined valve replacement and coronary revascularization may push the limits of the technique. It has been shown that the period of reperfusion should be greater than 5 minutes, to allow for ventricular recovery. In addition, the heart usually fibrillates during reperfusion and may have inadequate subendocardial blood flow. Topical hypothermia with a single cross clamped period appeared to add to the safety of ischemic arrest, but has not been consistently safe. Although some hearts tolerate 1½-2 hours of cold ischemia, others sustain severe damage.

The technique of ischemic arrest is still being used today, primarily for simple procedures like ASD repair, isolated valve replacement and for repair of some congenital cardiac lesions. During the late 1960s and early 1970s it was considered to be the best way to do coronary artery surgery because the distal anastomosis could be done during the ischemic period and the proximal (aortic) anastomosis could be done during reperfusion. However, in the early 1970s the technique of chemical cardioplegia gained popularity and now has replaced ischemic arrest as the most commonly employed technique of myocardial protection for coronary artery surgery.

III. Chemical Cardioplegia

Although hypothermia and ischemic arrest techniques reduce myocardial oxygen consumption from 5.59 cc/100 gm/min to 1.95 cc/100 gm/min, the "safe ischemic time" is still only 45-60 minutes at 22°C. While hypothermia reduces the basic metabolic rate of the myocyte and CPB reduces the energy required for ejection, energy is still required for myofibrillar contraction (ventricular fibrillation) and for maintenance of transmembrane ionic gradients. Because maintenance of high energy stores is critical to maintenance of myocyte integrity which in turn is critical to myocardial function, investigators in the early 1970s rediscovered the concept of chemical cardioplegia, the introduction of chemical agents into the coronary arteries to produce rapid diastolic arrest. The advantages of diastolic arrest can be seen in Table 1 and Figures 1 and 2. Once the energy consuming process of fibrillation is eliminated, myocardial oxygen extraction decreases by 85%, theoretically increasing the "safe ischemic period" sixfold.

Most cardioplegic solutions contain either potassium[15] and magnesium[22] or procaine[23] to promote rapid diastolic arrest. Both potassium and magnesium work

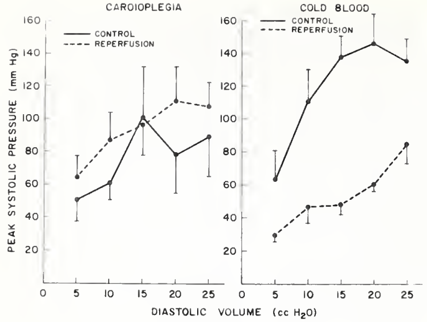

Figure 1
The experimental results obtained after two hours of aortic cross clamping in dogs are shown. Curves were obtained by inflating an intraventricular balloon in a stepwise fashion. The left hand graph shows that there is no change in the peak systolic pressure generated after cardioplegic myocardial protection. The right hand graph shows the deterioration after the intermittent administration of cold blood.[25]

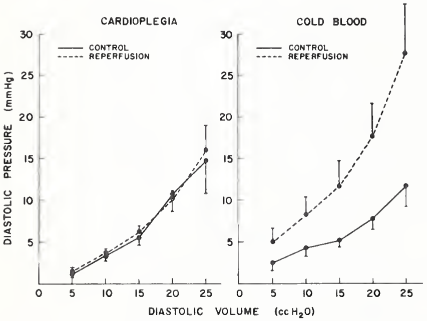

Figure 2
The change in compliance after two hours of aortic cross clamping is shown. As can be seen on the left, there is no change in compliance with cardioplegia, whereas the intermittent perfusion with cold blood results in a significant decrease in compliance.[25]

by blocking myocardial cellular depolarization. In a typical application, the patient is cooled to 28°C, the aorta is clamped and a 4°C cardioplegic solution is injected into the aortic root proximal to the aortic clamp. Most solutions contain 20-30 mEq of KCl combined with albumin or mannitol to create an iso-osmotic solution.[12] Other surgeons add procaine for its membrane-stabilizing properties,[23] glucose-insulin to supply some energy substrate or calcium antagonists[24] to prevent the theoretic calcium paradox on reperfusion. Others have used cold blood as a medium to transport the hyperkalemic cardioplegia solution.[25-28] Since the benefits of chemical cardioplegia and hypothermia are additive, topical hypothermia is induced by application of iced saline solution. The one disadvantage of cardioplegic arrest is that after twenty minutes, non-coronary collaterals wash out the cardioplegic solution and rewarm the heart.[29] For optimum protection, the cold cardioplegic solution must be reinfused every 20 minutes.

The advantages of cold cardioplegia are numerous. The surgeon has all the technical advantages of ischemic arrest, namely a quiet, bloodless operative field and also has the advantage of a soft flaccid heart, provided by diastolic arrest. The soft flaccid heart makes retraction easier, which makes technically demanding operations easier. In addition, the decreased energy requirements of the heart allow longer ischemic time with less ischemic injury.

Using current techniques, surgeons can routinely arrest the heart, deprive it of all coronary blood for over 2 hours, and restart it with minimal, if any, loss of ventricular function. Experimental and clinical studies have shown that after 2 hours of hypothermic cardioplegic arrest 1) there is no loss of ventricular function; 2) there is minimal, if any, depletion of myocardial ATP stores; and 3) there is good preservation of myocytic and capillary endothelial ultrastructure. Hypothermia reduces the metabolic rate and therefore decreases the energy loss of basic metabolism, while chemical cardioplegia eliminates the energy expended in contraction. There is even some indirect evidence that potassium may be important in maintaining myocyte membrane kinetics during ischemia and in rapidly restoring metabolic function after ischemia.[30] On a practical level, it provides an optimum operating environment.

The combination of chemical cardioplegia and topical hypothermia is the most popular technique for myocardial protection currently being used during cardiac surgery. For the combined procedure of aortic valve replacement and coronary revascularization, myocardial protection is put to the greatest test, because of the presence of coronary artery disease and ventricular hypertrophy. We have shown that cold chemical cardioplegia is superior to ischemic arrest and is coronary perfusion for this combined operation.[31]

Conclusions

Proper attention to myocardial protection has reduced the operative mortality for surgical valve replacement to less than 5% and for elective coronary artery surgery to less than 1%. Equally impressive has been the decrease in the perioperative infarction rate and the decreased need for pharmacologic and mechanical support after cardiopulmonary bypass.[31] In addition, the results of surgery in patients with severely impaired ventricular function have improved dramatically.

Improved understanding of the principles of myocardial protection, culminating in the use of cold chemical cardioplegia, has been one of the major advances in cardiac surgery over the last five years.

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Repair of Complex Congenital Cardiac Defects with the Valved Conduit

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ABSTRACT—We describe our experience with the valved conduit, which has made possible the correction of complex congenital cardiac defects involving the right side of the heart. From July 1974 to December 1979 we have inserted a valved conduit or porcine valve in 46 such patients. Eight had pulmonary atresia, seven had truncus arteriosus, eight had transposition of the great arteries with ventricular septal defect, and pulmonary stenosis. Ten underwent the "Fontan" procedure, thirteen underwent repair of Tetralogy of Fallot with conduit or porcine valve insertion. The operative technique used is illustrated. There were thus 46 patients undergoing these complex repairs with four early (< 30 days) deaths (8.6%). Ten were repeat intracardiac repairs or conduit replacements with one death. This experience indicates that the porcine xenograft valve, used in a conduit or beneath a patch, provides a satisfactory means of correcting lesions of the right side of the heart.

In 1965 Rastelli et al[1] first reported the establishment of continuity between the right ventricle and the pulmonary arteries using an external conduit of pericardium without a valve. In 1966, Ross and Somerville[2] described the repair of pulmonary atresia using a valve containing aortic homograft. Problems of procurement and sterilization made its use difficult. Long term follow up also revealed late calcification of the homograft, frequently resulting in stenosis and requiring reoperation. In 1973 use of a dacron conduit containing a gluteraldehyde preserved porcine valve was described[3] and became commercially available.*

The valve containing conduit has made it possible to reestablish continuity between the right ventricle and the pulmonary arteries in cases of pulmonary atresia[2] (Figure 1). Truncus arteriosus may also be treated using a similar technique[4] after disconnecting the pulmonary arteries from the truncus and closing the VSD (Figure 2). In addition, the complex of transposition of the great arteries with ventricular septal defect (VSD) and pulmonary stenosis can be repaired by redirecting the stream of blood from the left ventricle across the VSD and out the aorta beneath the VSD patch, while the conduit establishes continuity between the right ventricle and the disconnected pulmonary artery[5] (Figure 3). Repair of Tetralogy of Fallot in certain situations also requires use of a valved conduit or porcine valve in the pulmonary position. Another advance came with the use of the valved conduit to

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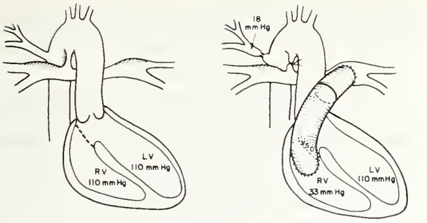

Figure 1
Left diagram illustrates findings in an 11 year old boy with pulmonary atresia, ventricular septal defect (VSD) and both pulmonary arteries perfused by a patent ductus arteriosus. The right upper lobe is supplied by a large artery arising from the descending aorta. Repair shown on right with closure of VSD and insertion of valved conduit from right ventricle (RV) to pulmonary artery. Collateral is banded. The pressures are shown.

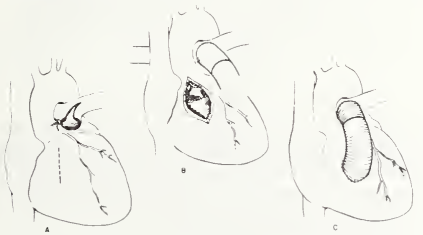

Figure 2
Repair of truncus arteriosus is shown. A—The pulmonary artery (PA) is disconnected from the truncus and the site closed primarily. An incision is made in the right ventricle (dotted line). B—The ventricular septal defect is closed with a patch and the valved conduit is anastomosed to the main PA. C—The conduit is sutured to the walls of the right ventricular incision.

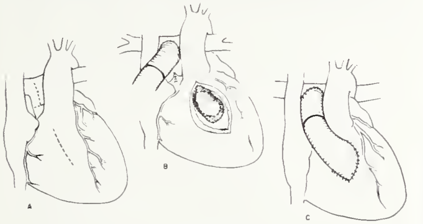

Figure 3
The procedure for repair of transposition of the great arteries, ventricular septal defect (VSD) and pulmonary stenosis is shown. A—The pulmonary artery (PA) is transected and an incision made in the right ventricle. B—The proximal stump of the PA is oversewn and the conduit sutured to the distal PA. The VSD is closed so that the left ventricle can eject into the aorta. C—The conduit is sutured to the walls of the right ventricular incision.

reestablish continuity between the right atrium and the pulmonary artery or right ventricle in cases of tricuspid atresia—the so-called Fontan procedure [6] (Figure 4)

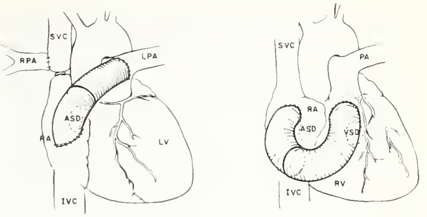

Figure 4
Left diagram shows "Fontan" procedure with previously placed superior vena cava (SVC) to right pulmonary artery (RPA) shunt. The atrial septal defect (ASD) is closed and a valved conduit placed between the right atrium (RA) and the left pulmonary artery (LPA). Right diagram shows the modified procedure with closure of the ventricular septal defect and placement of the conduit from the RA to the small right ventricle (RV).

which has also been applied to other complex lesions.[7]

We report our experience in the treatment of these complex lesions using the porcine valved conduit, between July 1976 and December 1979.

Management of Cardiopulmonary Bypass and Myocardial Protection

A membrane oxygenator was used for cardiopulmonary bypass (CPB) with moderate hemodilution (haematocrit 25-30%) and systemic hypothermia varying from a tympanic membrane temperature of 20°C to 28°C. In most cases a median sternotomy was used. Where a previously placed valved conduit was present, or in tricuspid atresia, with a previous median sternotomy, because of adherence of the conduit or right atrium to the sternum, a transverse bilateral thoracotomy was used, especially when the right chest had not previously been entered. In order to establish CPB, the ascending aorta was usually cannulated and the superior and inferior vena cava were cannulated via the right atrium. Where a previous superior vena cava to right pulmonary artery (Glenn) shunt had been performed, the superior vena cava was cannulated directly. Previous systemic to pulmonary artery shunts were occluded prior to instituting CPB. A previous Waterston shunt generally resulted in kinking of the pulmonary artery requiring reconstruction,[8 9] either with a pericardial patch or insertion of a graft from the conduit to pulmonary artery. In two patients previously placed Glenn shunts were taken down, using polytetrafluoroethylene grafts to reestablish continuity between the superior vena cava and the right atrium and between the main pulmonary artery and the right pulmonary artery. The ventricular septal defect was closed with a double velour dacron patch and continuous sutures of prolene. Myocardial protection was provided by the administration of cold blood cardioplegia (10 ml/Kg) containing 30 mEq KC1/1 every 20 to 30 minutes during cross-clamping.

Pulmonary Atresia

Eight patients with pulmonary atresia underwent repair. Six had a ventricular septal defect (VSD), which was also closed. Four had a previous Waterston shunt with kinking of the PA and required reconstruction using a pericardial patch in two. In two, grafts were placed from the valved conduit to the left pulmonary artery. In two, bronchial collaterals were ligated and in one where the collateral was the only supply to the right upper lobe, the artery was banded as shown in Figure 1, to avoid infarction of the lung.

There were no early deaths in this group. Four have undergone repeat catheterization and have been found to have right ventricular pressures of 30 to 45 mm Hg.

Truncus Arteriosus

Seven patients underwent repair of truncus arteriosus (Figure 2). The youngest was 6 weeks, weighing 4 Kg's, in whom a 12 mm conduit was successfully inserted. Two had undergone previous truncus repair but developed stenosis at the site of the small calcified conduit valve. They had also developed truncal regurgitation. In these patients, the conduit was replaced with a 30 mm valved conduit, the truncal valve was replaced and a tricuspid annuloplasty performed in one and a residual VSD and ASD closed in the second, with good early results. There was one death in this group, due to cardiac tamponade, which, we feel, was avoidable.

Transposition of the Great Vessels with VSD and Pulmonary Stenosis

The Rastelli procedure (Figure 3) was performed in eight patients, aged nine months to 19 years. Two were under one year of age, weighing 9 Kg. A 20 mm conduit was successfully placed in these patients (Figure 5). There were two deaths in this group. One in a 13 year old patient, who three years previously, had undergone a Mustard procedure and closure of a ventricular septal defect at another institution. This patient developed biventricular failure, more marked in the right ventricle. An attempt was made to use the anatomic left ventricle as the systemic ventricle, by reopening the ventricular septal defect and performing a Rastelli procedure. This patient died in a low output state.

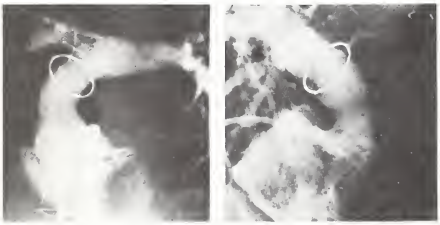

Figure 5
Angiograms of a 9 Kg infant after repair of transposition of the great arteries, VSD and pulmonary stenosis. As can be seen in PA and lateral views, a 20 mm valved conduit has been placed between the right ventricle and the pulmonary artery.

Tetralogy of Fallot

In the vast majority of cases, a valved conduit is not used in repair of Tetralogy of Fallot. It may be indicated in cases of virtual atresia of the outflow tract, with single pulmonary artery, with elevated PA pressures, where an anomalous left anterior descending coronary artery crossed the RV outflow tract and in some redo operations for Tetralogy of Fallot.

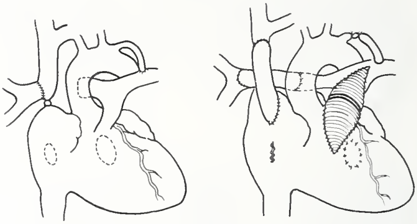

Figure 6
Shows the repair in an 18 year old girl with Tetralogy of Fallot who had a previous Glenn shunt. The ventricular septal defect (VSD) is closed and a porcine valve was placed beneath the outflow tract patch. Continuity between the superior vena cava and right atrium was established with a Goretex graft and a similar graft was inserted between right and main pulmonary arteries.

A valved conduit was used in four cases of Tetralogy of Fallot. The indication was a single pulmonary artery in one case. In two patients, the conduit was inserted because of virtual atresia of the pulmonary valve and infundibulum. In one patient, the conduit was inserted because of an anomalous left anterior descending coronary artery traversing the right ventricular outflow tract. In order to avoid damaging the coronary artery, an incision was made in the right ventricle (RV) below the artery and the conduit placed between the RV at this site and the pulmonary artery. There were no deaths in this group.

Recently we have modified our technique in those patients where a valve is indicated, including absent pulmonary valve syndrome, but excluding the patients with an anomalous coronary artery. In these patients, we now prefer to place a porcine valve beneath an outflow tract patch extending across the pulmonary annulus as shown in Figure 6. The advantage of this approach is that it allows the insertion of a larger sized valve and avoids the problem of compression of a conduit behind the sternum. Nine patients have undergone insertion of a porcine valve beneath an outflow tract patch, ranging in age from 9 months to 18 years. Seven were undergoing repeat operations following previous Tetralogy of Fallot repairs, while one aged 8 months had an absent pulmonary valve syndrome and one a previous Glenn shunt, which was taken down. There were no deaths in this series and all are doing well.

Fontan Procedures

Ten patients ranging in age from 7 to 23 years underwent a Fontan procedure. Six had tricuspid atresia, while one had mitral atresia, one a univentricular heart with total anomalous pulmonary venous drainage, one a ventricular septal defect with a crisscross relationship which could not be septated, and one pulmonary atresia with severe right ventricular and tricuspid hypoplasia. In seven patients the valved conduit was placed between the right atrium and pulmonary artery and in three patients, between the right atrium and right ventricle (Figure 4). Three patients had previous Glenn shunts (superior vena cava to right pulmonary artery) and in two, it was performed at the time of the Fontan procedure.

There was one early death in this series, in the patient with total anomalous pulmonary venous drainage.

Conclusions

In this report we have concentrated on the use of the valve bearing conduit in reestablishing continuity on the right side of the heart. In many types of congenital heart disease it has been used to reestablish continuity between the functional right ventricle and the pulmonary arteries. An additional modification in which a pulmonary valve is placed beneath a large right ventricle outflow tract patch is also described. In the case of the Fontan procedure this may be between the right atrium and right ventricle or pulmonary artery. This series with 3 early deaths among 45 patients, also shows that with newer methods of myocardial protection these complex procedures can be performed with an acceptably low mortality rate and with good long term results. Ten patients in this series had undergone previous intracardiac repair, with only one death in a patient with end stage myocardial dysfunction. This low mortality is promising, as it may become necessary to replace the valved conduits as they are outgrown, or undergo deterioration, as was done successfully in three patients in this series.

The availability of the dacron graft with the gluteraldehyde preserved porcine xenograft has made possible the repair of previously uncorrectable complex congenital cardiac anomalies.

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Aortic Dissections and Disruptions

HORACE C. STANSEL, JR., M.D.

ABSTRACT—Aortic dissections and disruptions are frequently encountered by the cardiac surgeon as a serious acute problem. Due to the marked increase in the vehicle accidents on our high speed highways and the spectacular increase in the interest of the management of trauma, disruption of the thoracic aorta is being recognized far more frequently than it was only a few years ago. It is now clear that many of these patients can be salvaged by aggressive surgical management. This review of the experience at the Yale-New Haven Hospital reveals some of the problems related to the management of these lesions and emphasizes the part that medical management has to play in the therapy of some types of acute aortic dissections.

Aortic Dissection

Since the 1955 report of DeBakey, Cooley, and Creech,[1] describing a fenestration procedure for descending aortic dissection, the accepted methods of management of this lesion has been in a state of change. For purposes of discussion, it is useful to accept recent nomenclature wherein aortic dissections are divided into two categories.

Type I is any dissection that begins immediately above the aortic valve and may extend proximally and distally for any distance. Type II includes those dissections that begin distal to the left subclavian artery and extend distally. This distinction is extremely important because of the significance of the two areas of dissection in terms of mortality and management, either by medical or surgical means. Type I dissections necessarily involve the ascending aorta and frequently dissect in a retrograde fashion to displace the aortic valve producing aortic insufficiency. This is a highly lethal lesion and, at the present time, surgical management is indicated for all Type I lesions with aortic regurgitation. The surgical management includes either aortic valve replacement or occasionally resuspension of the aortic valve so as to insure its competence and reconstruction of the ascending aorta. It is clear that non-surgical management of this lesion is ineffective and should not be entertained in any patient with evidence of aortic regurgitation. The surgical management is complex because of the friable state of the tissues involved and the frequent association of coronary artery dissection. Recent techniques involving coronary artery grafting or reimplantation into the graft have improved the surgical results but the lesion remains a formidable one.

Type II dissections beginning beyond the left subclavian artery and extending distally have an entirely different connotation. The indications for surgical intervention in these lesions include major arterial obstruction such as the superior mesenteric, renal, or lower extremity vessels or free rupture of the thinned out aortic wall. In those patients without any of the above mentioned complications requiring surgical intervention, it is now clear that medical management has much to offer.[2] This medical management includes antihypertensive agents to lower blood pressure, and drugs such as propranolol utilized to diminish the intensity of the systolic thrust of the left ventricle.

Experience has now confirmed that many patients, when treated vigorously with the hypotensive regimen briefly described above, will go on to stabilize their dissection and live for many years. The diagnosis of an aortic dissection should be highly suspected from the history and a plain chest x-ray. Although the vast majority of patients will present with excruciating chest pain as an initial event, we have seen a few patients in whom chest pain was a relatively insignificant feature of the symptom complex. A plain chest x-ray will usually reveal some dilitation of the aortic knob or other changes that will suggest a dissection. The

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definitive diagnostic tool, of course, is an aortogram which will usually clearly demonstrate the area of dissection and the presence or absence of aortic regurgitation. It is important that the aortogram be followed through the entire extent so as so appreciate the involvement of major aortic branches. Only after the performance of a satisfactory aortogram can an intelligent decision be made regarding the appropriate treatment.

We have recently reviewed the experience at the Yale-New Haven Hospital in the management of acute aortic dissection.[3] A review of this experience revealed that of the Type II dissections involving only the descending thoracic aorta, there were 19 patients treated medically with 15 (or 79%) long-term survivors. Of the 12 patients treated surgically, only 7 (or 58%) lived for at least one year following the surgical procedure. This experience has been similar to that reported by other authors in the literature.[4 5 6 7] Ascending aortic dissection, however, is clearly a surgical lesion. A review of our experience reveals that we have seen 15 patients, who for various reasons were treated with only medical antihypertensive regimens. Only three of this group of patients left the hospital. Similarly, five of the nine patients who underwent graft replacement and aortic valve replacement or reconstruction survived. It is, therefore, clear that the distinction between Type I and Type II aortic dissection is a very important judgement to be made early. For all practical purposes, all Type I dissections should be operated upon as soon as possible with attention being directed toward restoration of aortic valve competence and maintenance of coronary arterial flow. Surgical intervention in Type II lesions should be limited to those lesions in patients with occlusion of major arterial branches of the aorta or free rupture. All other Type II dissections can be treated with vigorous antihypertensive programs with a very high expected survival rate.

Aortic Disruption

The obvious increase in high speed travel on our highways has been associated with a predictable increase in the incidence of more violent deceleration collisions. The descending thoracic aorta, being firmly fixed in the posterior mediastinum by intercostal arteries, pleura and other tissues, is essentially immobile. The aortic arch and heart, however, are relatively mobile lying in the superior mediastinum. During rapid deceleration the momentum of the heart and aortic arch may carry these structures in any direction and often results in tearing or indeed transecting the descending thoracic aorta at the point of fixation just distal to the left subclavian artery. This injury may result in rapid and immediately fatal hemorrhage or it may be contained by the mediastinal pleura allowing time for a definitive diagnosis and therapy. The incidence of this injury is estimated to occur in 10-15% of all automobile crash fatalities. It is well-known that 80% or more of these patients will die of the injuries before surgical repair can be achieved. A few will survive the injury and develop chronic aneurysms at the site of the aortic tear with survival for many years. No age group is exempt and any sort of decelerating trauma can produce this lesion.

At the Yale-New Haven Medical Center, we have had experience with 27 patients in whom a premortem diagnosis of traumatic rupture of the thoracic aorta has been made and this experience forms the basis for this report. (Figure 1)

Twenty-three of these patients were involved in either automobile or motorcycle accidents, three were injured during falls, and one patient presented with a transected aorta suffered after striking a tree while skiing. One patient, a ten year old child, expired during the performance of an aortogram in the radiology suite and six other patients died either during or soon after operative intervention. The causes of death in these other patients include one patient who died of an aortobronchial fistula, one patient died during attempted resection of a coarctation created at the initial repair, one patient died a brain death that possibly could be related to the perfusion and the remaining patients died of complications of their initial injury.

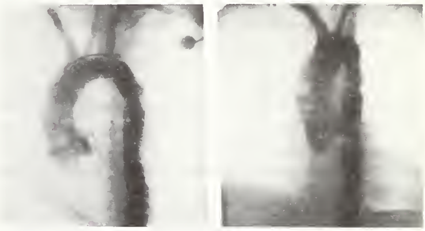

Figure 1

This aortogram reveals the rather classic location of a complete transection of the descending thoracic aorta occurring after a deceleration injury. It should be noted that the dye column is completely confined by the overlying pleura in spite of complete interruption of the integrity of the aortic wall and this patient subsequently underwent an uneventful repair.

There were ten patients who were repaired utilizing some form of cardiopulmonary bypass, usually venoarterial bypass and, of these, three patients failed to survive. Of the 16 patients operated upon utilizing the Gott shunt, four died. It is of interest that there were two patients in whom the proximal tear occurred at the level of or proximal to the left subclavian artery such that conventional use of the Gott shunt was made extremely difficult and necessitated the use of cardiopulmonary bypass.

Serious complications as a result of the repair occurred in three patients in whom permanent paraplegia developed. It is of interest that two of these patients were repaired utilizing the Gott shunt and one was repaired under venoarterial bypass. A review of these three patients does not reveal any clue regarding technical errors that would have been likely to have produced the spinal cord injury and, indeed, in two of the patients it was specifically noted that it was not necessary to even control one intercostal artery because of the location of the tear. The incidence of this complication as reported in the literature[8] is approximately 5% regardless of the method of repair.

The surgical management of traumatic disruption of the thoracic aorta simply involves repair of the aortic disruption with or without the interposition of a synthetic arterial graft. Alley,[9] some years ago, advocated the primary anastomosis of aortic disruption so as to avoid the use of prosthetic materials. In our experience, however, we have not seen a patient in whom it was deemed advisable to attempt a primary repair and, accordingly, all of our patients have been reconstructed with a small segment of prosthetic arterial graft. Initial experiences in repair of this lesion involved the use of cardiopulmonary bypass but this is frequently associated with many problems related to the use of heparinization and in these patients, poses distinct risks.

The development of the Gott heparinized tube has provided a method whereby the usual tear can be reconstructed while maintaining adequate decompression of the ascending aorta and satisfactory perfusion of the descending thoracic aorta. We have encountered a few patients in this series, however, where the location of the aortic tear rendered conventional use of the Gott tube extremely difficult or impossible. A few authors have suggested that simple cross clamping of the aorta for the brief time necessary to reconstruct the transected aorta is relatively safe but certainly the vast experience reported in the literature would suggest that some form of bypass, either active or passive, is desirable.

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Surgical Treatment of Ventricular Aneurysms and Arrhythmias Associated with Coronary Arterial Occlusive Disease

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ABSTRACT—Ventricular aneurysms and tachyarrhythmias are serious complications of coronary arterial occlusive disease and infarction. The hemodynamic and other consequences of aneurysm may lead to cardiovascular deterioration and constitute indications for resection of the aneurysm and concomitant revascularization of arteries to ischemic areas of the myocardium. When the aneurysm is well defined and involves only one or two walls of the left ventricle, the results are gratifying and the hospital mortality low (7.5%). When the scar is diffuse, large, and consists of a mixture of scar tissue intermingled with noncontracting strands of muscle, the results of resection are disappointing. Malignant ventricular arrhythmias more often than not arise from tissue adjacent to the scar rather than the scar itself, hence the high incidence of recurrent ectopy in patients treated with aneurysmectomy and/or bypass grafting only. Recent developments in cardiac electrophysiology, including programmed electrical stimulation for induction of tachyarrhythmias, and endocardial and epicardial mapping, allow for evaluation of therapeutic modalities in such patients. Those with ventricular arrhythmias refractory to medical therapy, including pacing, are candidates for surgical therapy. Further followup is required to establish which procedure—encircling endocardial ventriculotomy or subendocardial resection—is most widely applicable, technically feasible, and highly successful.

Spontaneously occurring ventricular arrhythmias in the absence of demonstrable coronary artery disease appear to have a negligible effect on longevity.[1] However, when combined with coronary artery disease or occurring during myocardial infarction, they carry a very serious prognosis.[2-5] With the advent of myocardial revascularization, recent interest has increased in trials of surgical therapy in patients with ventricular arrhythmias complicating coronary occlusive disease. Such trials have included myocardial revascularization in patients surviving sudden coronary deaths without evidence or with a low incidence of periarrest myocardial infarction,[5-7] and bypass grafting and/or myocardial resection in patients after infarction.[5,8,9] The development of electrode catheter techniques of intracardiac electrical recording and programmed electrical stimulation of the heart in the past few years has opened a new approach to the diagnosis, evaluation, and management of cardiac arrhythmias. These methods allow evaluation of the function of the sinus node and the atrioventricular conduction system and, of more practical importance, determination of the mechanisms of supraventricular and ventricular tachycardia as well as selection of the most effective therapeutic modalities in these arrhythmias.

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A left ventricular aneurysm is a distinct area of scarring which results from the healing of a transmural myocardial infarct. Not all akinetic or dyskinetic areas seen on left ventricular angiography necessarily turn out to be true ventricular aneurysms at operation. Many of these angiographically diagnosed "aneurysms" prove to consist of a mixture of fibrotic patchy scarring and ischemic myocardium at the time of surgical exploration. Ventricular aneurysms may or may not be associated with severe ventricular arrhythmias, and may require surgical treatment on the basis of their own hemodynamic consequences or, more often, because of their effect in combination with occlusive lesions in other coronary arteries.

This communication briefly reviews the current state of the art in the field of surgical treatment of ventricular arrhythmias and aneurysms as well as our experience at the Yale New Haven Medical Center with the surgical therapy of these complications of coronary arterial occlusive disease.

Ventricular Aneurysms

A large aneurysm of the left ventricle may impose a severe strain on the hemodynamic function of the remainder of the ventricle. This results from the systolic expansion of the aneurysmal wall (paradoxical contraction), increased ventricular size resulting in increased fiber length, decreased fiber shortening and diminished stroke volume, elevated left ventricular end-diastolic pressure and volume, with a depressed ejection fraction. When these changes are superimposed on an already ischemic myocardium due to coronary atherosclerosis in the vessels supplying non-infarcted muscle, cardiac decompensation often follows. The increased work demands of the functional myocardium may also result in, or contribute to, the development of angina. In addition to arrhythmias, an aneurysm may be associated with mural thrombi and embolization.

A hemodynamically significant aneurysm resulting in one or more of the above manifestations should be treated by excision of the aneurysm and revascularization of any remaining ischemic myocardium. In our experience, this approach has been associated with an operative mortality of 7.5% (3/40) when the aneurysm is localized to one or two walls of the left ventricle. Excellent functional results are obtained on long-term follow-up.

Aneurysms involving more than two walls of the left ventricle are associated with a very poor prognosis, regardless of whether they are treated surgically or medically. Not infrequently, these aneurysms appear at the time of operation to consist of thinned out hypokinetic or akinetic areas which quite often contain non-contracting but recognizable strands of muscle intermingled with scar tissue. The hemodynamic consequences and resulting symptomatology of such infarcted areas are similar to those of more defined and well localized true aneurysms, leading to cardiac dilation and increased wall tension with resultant overstretching of the remaining fibers, decreased ejection fraction and increased end-diastolic pressure and volume. Patients with such a diffuse and extensive picture, in whom a margin suitable for resection cannot be readily identified, have a very poor prognosis. In our experience, surgical resection is associated with an extremely high mortality, and it is wiser to graft coronary vessels without attempting myocardial resection. The ultimate remedy in these patients may be cardiac transplantation. Unfortunately, left ventricular angiography cannot always be counted upon to distinguish between true aneurysms and diffuse areas of myocardial scarring.

Malignant Ventricular Arrhythmias

While aneurysmectomy and bypass grafting have been widely used to treat malignant ventricular arrhythmias which are refractory to medical therapy, the results have not been uniform, and some investigators question the use of these procedures when the sole indication is arrhythmias.[10 11] In our experience with 35 patients with refractory ventricular arrhythmias and previous documented infarction who were treated by grafting and/or aneurysmectomy (as well as correction of other mechanical defects when present), 19 of 26 long-term survivors continued to have recurrent ectopy.[5] The recurrent arrhythmia in these patients may be due to both reentry and automaticity mechanisms.

Our current approach to these recurrent ventricular arrhythmias is based on the recent electrophysiologic developments mentioned earlier and an improved understanding of the mechanisms of these arrhythmias.

Current Approach to Malignant Ventricular Arrhythmias

These patients usually have coronary artery occlusive disease and myocardial scar tissue with or without aneurysmal changes in the region of their old infarct. The recurrent sustained ventricular tachycardia poses a challenge to the clinician in selecting the most effective mode of therapy. Reproducible initiation of the ventricular tachyarrhythmia by programmed electrical stimulation provides a tool for evaluation of different antiarrhythmic drugs and/or a pacemaker in prevention or termination of the arrhythmia. Following the initiation and termination of ventricular tachycardia by programmed electrical stimulation in the catheterization laboratory, intravenously administered antiarrhythmic drugs are tested to determine their effectiveness in abolishing the appearance of the arrhythmia through programmed electrical stimulation. A variety of antiarrhythmic drugs are available, including procainamide, quinidine, lidocaine, phenytoin, disopyramide, propranolol, aprenidine and tocainide, as well as new experimental antiarrhythmic agents such as amiodosone. Similarly, the ability of overdrive or underdrive pacing to terminate the ventricular arrhythmia is assessed. Based on these electrophysiologic studies, the patient is started on the antiarrhythmic agent which seems to be most effective; if pacing is indicated, an appropriate pacemaker, usually using the transvenous endocardial route, is implanted.

In 10 to 30% of patients with malignant ventricular arrhythmias, however, an antiarrhythmic regimen and/or pacing prove to be ineffective. These patients with refractory ventricular tachyarrhythmia become candidates for surgical therapy prior to which they undergo more detailed electrophysiologic evaluation, including endocardial mapping of both ventricles during induced ventricular tachycardia to locate the site of origin of the arrhythmia.[13] This is done by catheter mapping of various sites in both ventricles to find the earliest site of electrical activation during ventricular tachycardia or to locate a site of continuous electrical activity close to the area of old infarction. The origin of the refractory tachycardia in the majority of the patients is in the left ventricle regardless of the morphology of the ectopic QRS on surface electrocardiogram.

The surgical approach in these selected patients requires cooperation of the electrophysiologic and surgical teams in the operating room to achieve direct epicardial and endocardial mapping during induced ventricular tachycardia in the open chest. Two operative approaches have been described with a high rate of success in abolishing the arrhythmia. The first, developed in France, utilizes an encircling endocardial ventriculotomy in the wall of the left ventricle surrounding the scar.[14 15] The other, based on the observation that the site of origin of the arrhythmia is outside the area of scar tissue itself, in the subendocardial region of healthy myocardium near the scar, resorts to resection of the endocardium at the identified site of origin of the arrhythmia.[16] The latter approach has the advantage of less interference with ventricular function. Relatively short follow-up has shown excellent results with both approaches in controlling the arrhythmia, but further follow-up is required to establish which procedure—encircling endocardial ventriculotomy or subendocardial resection—is most widely applicable, technically feasible, and highly successful.

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End Stage Heart Disease, Ventricular Support Systems, and Cardiac Transplantation

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ABSTRACT—Many patients present at a time when severe myocardial impairment has already occurred. They pose a challenging problem, because medical therapy is usually ineffective and survival poor. In some of these patients, symptoms can be alleviated and survival prolonged if there is a correctable lesion such as bypassable coronary artery disease, valvular heart disease, or a resectable aneurysm. These patients may need intraaortic balloon counterpulsation or the use of a ventricular assist device to wean them from cardiopulmonary bypass and support the circulation until myocardial recovery occurs. In other patients with severe ventricular impairment and heart failure, cardiac transplantation—and in the future, the artificial heart—may offer the only hope of prolonging life and making it tolerable.

End Stage Heart Disease

Patients are included under this loose definition when it is apparent that severe cardiac impairment has occurred which will result in death of the patient should it progress further. Generally, this is due to severe myocardial dysfunction secondary to long-standing valvular or coronary artery disease, or it may be due to a primary myocardial disease, as in the various cardiomyopathies. At this stage, patients are usually severely symptomatic and the prognosis without surgery is dismal, and in some categories can be measured in terms of months. At the same time, the risks of surgery are increased because of inadequate myocardial reserve. With the advent of improved methods of myocardial protection, the operative mortality has decreased in this difficult group of patients. Faulkner for example[1] compared a group of patients with coronary artery disease and ischemic cardiomyopathy resulting in an ejection fraction of less than 30%. At two years, the survival of the medically treated group was 47% versus 83% for the surgically treated group. The operative mortality was 4%.

Because the myocardial reserve is so limited, these patients may require additional support in order to be weaned from cardiopulmonary bypass. In most patients, the intraaortic balloon counterpulsation device (IABC) is adequate[2,3] but in a small number, the heart is unable to support the circulation. In order to salvage these patients who would otherwise die in the operating room, various left ventricular or biventricular assist devices have been developed, which can support the circulation until myocardial recovery occurs.

In other patients with severe myocardial impairment, corrective surgery may be impossible, as in the patient with a cardiomyopathy. In this situation, cardiac transplantation and in the future, the artificial heart may be the only available method of prolonging life. Initial clinical results show that it is possible to support such patients with intraaortic balloon counterpulsation until heart transplantation can be performed.[4]

Left Ventricular Assist Devices

Indications

There is a small group of patients who sustain myocardial injury at the time of cardiac surgery and who cannot be weaned from cardiopulmonary bypass despite the use of intraaortic balloon counterpulsation.[2,3] Provided that the technical goals of the procedures have been realized and there is no uncontrolled haemorrhage, the device is used to support the circulation until myocardial recovery has occurred. As oppos-

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ed to intraaortic balloon counterpulsation which assists the damaged heart these devices can take over the entire cardiac output and temporarily replace either right or left ventricular function, or both.

Myocardial recovery can occur in most patients after the initial result, provided that they can be supported until this occurs. This is suggested by the numbers of patients who have survived cardiac assistance and who have adequate long term ventricular function. We have shown,[3] in patients who have required intraaortic balloon counterpulsation to be weaned from cardiopulmonary bypass that long term ventricular function is similar to that found preoperatively indicating a largely reversible component in the acute injury.

Devices

Many devices have been designed and evaluated experimentally. Those used clinically may be divided into left ventricular to aortic and left atrial to aortic devices, depending on the site of the drainage cannula. The advantage of the left ventricular over the left atrial cannula is that the device may thereby lower left ventricular pressures to less than systemic levels (Figure 1) which has been shown to reduce myocardial oxygen consumption to a greater degree and to better protect the myocardium from ischemia.[5]

Devices may also be subdivided into those which employ a simple roller pump[6 7] and those which utilize a sac type of pump or "artificial ventricle" driven pneumatically[8] (Figure 2). The latter pumps have been placed intraabdominally and in the parathoracic position.[8 9] A centrifugal device[10] is also undergoing clinical evaluation.

Clinical Results

Because of its simplicity we have employed a simple roller pump with silastic tubing for cardiac assistance.[7 11] This device has been used in seven patients, ranging in age from two weeks to 46 years. All were successfully weaned from bypass. Two patients were successfully weaned from the device with recovery of ventricular function. One is alive and well three years postoperatively, while the other died from sepsis two weeks postoperatively. The remaining patients remained dependent on the device or developed right ventricular failure and died.

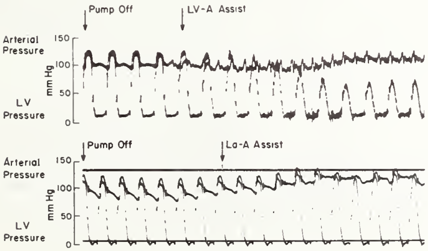

Figure 1
The upper panel shows the arterial pressure and left ventricular (LV) pressures before and after the institution of left ventricular to aortic (LV-A) assistance. As can be seen LV pressure is reduced to levels well below the arterial pressure. In the lower panel despite the institution of left atrial to aortic (La-A) assist, the LV pressure remains at systemic levels.

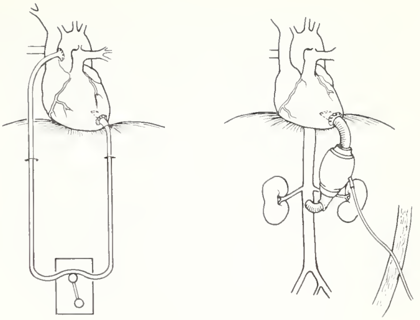

Figure 2
Two forms of left ventricular assist devices are shown. On the left the simple roller pump with silastic tubing and an LV apical cannula with a teflon felt lining is shown. The perfusion cannula is that described by Litwak[6] with a skirt which is sewn to the ascending aorta. The cannulae are brought out through the skin and can be permanently implanted. On the right the intraabdominal left ventricular assist device described by Norman and associates[12] is shown. The pump is placed in the abdomen and the pneumatic drive line is brought out through the skin. With recovery the pump is removed leaving the LV apical cannula in place.

Experience with the sac like device has also shown a high hospital mortality, both with the intraabdominal device[12] and the parathoracic device.[13 14]

Although it is clear that all these patients would almost certainly have died without the device it is disappointing that more could not be salvaged. Analysis of the clinical experience has shown that in many cases the heart recovers, but that the patient then succumbs to other severe systemic complications, such as sepsis, cerebral damage, renal or hepatic failure. This is often thought to be due to the prolonged period during which attempts are made to wean the patient from bypass, resulting in periods of inadequate systemic perfusion and high venous pressures.

Where assistance has been instituted promptly, survival was increased. Litwak and associates,[6] for example reported five long term survivors among eighteen patients undergoing left atrial to aortic assistance with a roller pump and silastic tubing.

Conclusions

Left ventricular assist devices are still in an early stage of development and clinical application. If future experience shows that they can be safely used with an acceptable rate of patient salvage, they may even further reduce the risks of open heart surgery. They may make it possible to operate on patients with end stage heart disease with severe left ventricular impairment with a greater hope of survival.

Cardiac Transplantation

Introduction

Twelve years have now passed since Barnard and associates performed the first human transplant in South Africa.[15] After initial widespread enthusiasm and activity, the procedure became confined to only a few centers, most being performed at Stanford University by Shumway, Stinson and associates.[16]

Indications and Contraindications

Because of the dangers of immunotherapy, heart transplantation has been used only in patients with end stage heart disease for whom medical therapy has been exhausted and conventional surgical therapy is not indicated, and in whom the chances of survival for more than a few months without transplantation are considered low. Because older patients tolerate immunosuppression poorly, patients over 50 years are generally not accepted. Early experience demonstrated that the donor heart could not tolerate the acute pressure load due to high pulmonary vascular resistance. For this reason, patients with fixed pulmonary vascular resistance of greater than 8-10 Wood units are not considered for transplantation. The presence of infection contraindicates transplantation until cured because of the dangers of immunosuppression, and a pulmonary infarct less than one month old is considered a contraindication because of the likelihood of infection at the site of the infarct. Systemic diseases such as insulin-requiring diabetes mellitus and severe hepatic dysfunction are also considered contraindications.

Techniques

The donor heart is usually harvested from a patient declared dead on the basis of brain death. A recent advance has involved the removal of the donor heart at a distant site and its transportation by air to the recipient. This has increased the area from which donor hearts can now be harvested.[17]

The heart may be transplanted either orthotopically, with removal of the recipient's heart, or used as an assist heart in which case the recipient heart is left in place and connections made between the left atria and aortas of the two hearts.[18] This latter method has the potential advantage of making the donor heart more expendable, should severe rejection occur, and may facilitate repeat transplantation at a later time. Most transplants performed today are orthotopic and the greatest long term experience has been obtained using this method.

Treatment of Rejection

The maintenance immunosuppression used include azathioprine and prednisone. In addition, rabbit antithymocyte globulin has been found to be effective in preventing rejection. The transvenous endomyocardial bioptome has facilitated the identification and treatment of rejection as the ventricular biopsy may precede other signs of rejection such as the fluctuations in electrocardiographic voltage and axis, atrial arrhythmias, the presence of a ventricular gallop, hypotension, and mild fever.

The ability to monitor therapy also holds promise of improving the results of transplantation. Such tests include measurement of circulating thymus-derived lymphocytes (T-cells) and measurement of antilymphocyte serum. Oral anticoagulants have been shown to retard the development of accelerated coronary arteriosclerosis in the graft and are now used routinely.

Results

At Stanford the one year survival is 68%, and 56% are alive at 5 years. Most of the survivors have returned to an active life (Class I NYHA) and many are employed.

Conclusions

Clinical experience has now demonstrated that cardiac transplantation offers a rational form of therapy for patients with end stage heart disease whose prognosis is otherwise measured in months. It remains, however, a formidable undertaking and presents unresolved problems in terms of difficulties of organ procurement, high cost, and public acceptance.

Total Artificial Heart

The first total artificial hearts were implanted by Kolff in 1957 in dogs who survived a few hours. Today there are calves who have been kept alive with orthotopic insertion of a total artificial heart for more than 210 days.[19] Problems with pump design, biomaterials, and thromboembolism have not been completely resolved. In addition, the drive systems have not been refined to the point of implantation. A drive line, either pneumatic or electric, must therefore be brought out through the skin to power the implanted heart.

The artificial heart has definite advantages over heart transplantation. It solves the problem of organ procurement as it is estimated that there are about 1.4 million people in America and Europe dying of cardiac failure yearly, many of whom might be candidates for transplantation or an artificial heart. The need, therefore, will continue until future developments make such a device feasible.

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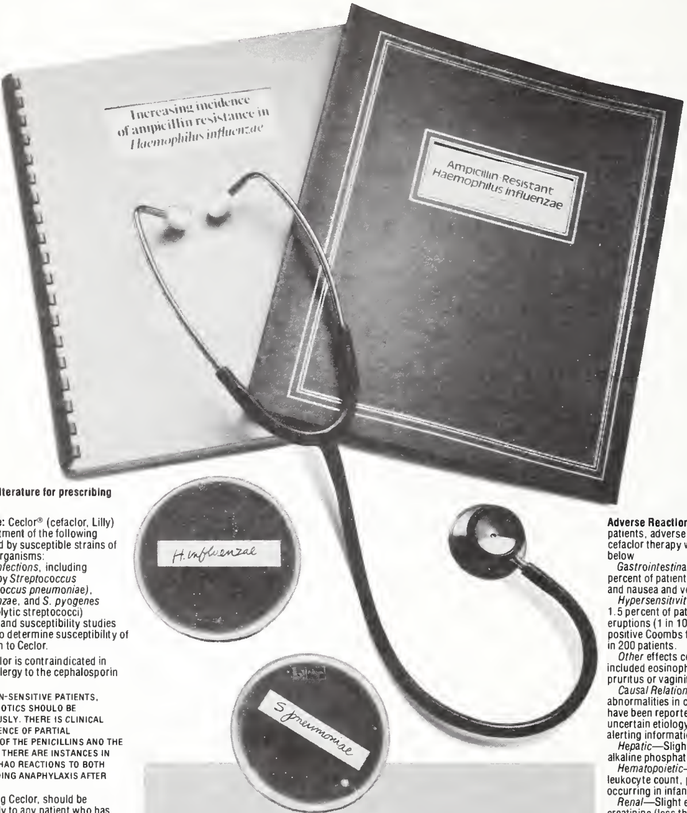
A Motion in a Circle

But what remains to be said upon the quantity and source of the blood which thus passes is of so novel and unheard of character, that I not only fear injury to myself from the envy of a few, but I tremble lest I have mankind at large for my enemies, so much doth wont and custom, that become as another nature, and doctrine once sown and that hath struck deep root, and respect for antiquity influence all men: still the die is cast, and my trust is in my love of truth, and the candour that inheres in cultivated minds. And sooth to say, when I surveyed my mass of evidence, whether derived from vivisections, and my various reflections on them, or from the ventricles of the heart and the vessels that enter into and issue from them, the symmetry and size of these conduits—for nature doing nothing in vain, would never have given them so large a relative size without a purpose—or from the arrangement and intimate structure of the valves in particular, and of the other parts of the heart in general, with many things besides, I frequently and seriously bethought me, and long revolved in my mind, what might be the quantity of blood which was transmitted, in how short a time its passage might be effected, and the like; and not finding it possible that this could be supplied by the juices of the ingested aliment without the veins on the one hand becoming drained, and the arteries on the other getting ruptured through the excessive charge of blood, unless the blood should somehow find its way from the arteries into the veins, and so return to the right side of the heart; I began to think whether there might not be a MOTION, AS IT WERE, IN A CIRCLE. Now this I afterwards found to be true.

—William Harvey, *Motion of the Heart,* VIII

An added complication... in the treatment of bacterial bronchitis*



Brief Summary.
Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS TO BOTH DRUG CLASSES (INCLUDING ANAPHYLAXIS AFTER PARENTERAL USE).

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Precautions: If an allergic reaction to cefaclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of cefaclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such a condition, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Usage in Pregnancy—Although no teratogenic or antifertility effects were seen in reproduction studies in mice and rats receiving up to 12 times the maximum human dose or in ferrets given three times the maximum human dose, the safety of this drug for use in human pregnancy has not been established. The benefits of the drug in pregnant women should be weighed against a possible risk to the fetus.

Usage in Infancy—Safety of this product for use in infants less than one month of age has not been established

Some ampicillin-resistant strains of Haemophilus influenzae—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Ceclor.[1-6]

In clinical trials, patients with bacterial bronchitis due to susceptible strains of Streptococcus pneumoniae, H. influenzae, S. pyogenes (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Ceclor.[7]

Ceclor®
cefaclor

Pulvules®, 250 and 500 mg

Adverse Reactions: In clinical studies in 1493 patients, adverse effects considered related to cefaclor therapy were uncommon and are listed below

Gastrointestinal symptoms occurred in about 2.5 percent of patients and included diarrhea (1 in 70) and nausea and vomiting (1 in 90).

Hypersensitivity reactions were reported in about 1.5 percent of patients and included morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs tests each occurred in less than 1 in 200 patients.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory tests results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200). [070379R]

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*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.[8]

Note: Ceclor® (cefaclor) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285.

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Efficacy, Safety, and Health Care Policy

DAVID BANTA, M.D., M.P.H. AND CLYDE J. BEHNEY, M.B.A.

Why the seemingly sudden explosion of interest and concern about medical technology? Problems of lack of adequate knowledge about the benefits and costs of such technologies have been discussed for many years. There have been several legislative approaches to assuring the availability of appropriate technologies to all citizens in the past few years. Nonetheless, problems concerning the development, evaluation, diffusion, and use of these technologies have become, in the space of four or five years, politically prominent.

Not surprisingly, the basic reason for this recent concern is the rapid rise in the cost of medical care and the resulting drive for cost containment. Some people have looked at technology as a principal culprit behind rising costs and have proposed its control as an approach to slowing the increase. We believe, however, that the magnitude of the cost increases is more appropriately "blamed" on the structure of the medical care system, and that technology has been inappropriately or at least inordinately blamed. In terms of technology, then, we are more concerned with the question of how and on what money is spent. Put another way, what is the effectiveness and cost-effectiveness of the various new and established medical technologies?

This question began to concern us at the Office of Technology Assessment (OTA) during 1975. OTA is a research agency of the U.S. Congress that was developed by legislation that passed in 1972. The legislation was the result of general concerns in the Congress about lack of access to useful information on technological advance and of specific concerns focusing on the development of the Supersonic Transport (SST). The Health Program was developed beginning in 1975, after discussion and approval of OTA's Congressional Board.

Even before the development of the OTA Health Program, OTA staff had discussed health policy concerns with staff of important Congressional committees. Those discussions led to a letter dated February 6, 1975 to OTA from Senators Kennedy, Williams and Javits that contained the following request: "A problem crossing the boundaries of both cost and quality concerns the use of new technology and procedures in health care. Before new drugs can be used, proof of efficacy and safety must be provided. However, no such legal requirement applies to new technologies and procedures . . . We request the OTA to establish a panel of outstanding individuals to examine current Federal policies and current medical practices to determine whether a reasonable amount of justification should be provided before costly new medical technologies and procedures are put into general use."

Three studies resulted from that request, all of which were done with the assistance of expert panels.[1 2 3] These studies have produced a great deal of knowledge. Perhaps the key point is that we have become aware that medical technologies can and often do diffuse into use and continue to be used with little relation to their demonstrated efficacy, safety, or costs. Furthermore, technologies of benefit to some patients or under certain conditions of use are often indiscriminately used. We will illustrate these problems through a series of cases.

The first case is gastric freezing for peptic ulcer. A prominent surgeon developed and promoted it, and there were many enthusiastic professional and press accounts. It was featured in *Time* magazine, for example. A private company, Swenko, developed a machine and marketed it vigorously. In all, 2500 machines were sold and an estimated 25,000 procedures were done. However, clinical experience was not very positive, and many patients had complications such as gastric hemorrhage. Sales of the machine peaked in 1963 and then began to fall. Subsequently, several good scientific studies of gastric freezing were done that showed the procedure to be of *no* clinical

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benefit. However, these studies had little impact, because the procedure had already largely gone out of use through unfavorable clinical experience. It had been largely abandoned by 1966. Total cost was considerable, not only for the machines and the medical care, but through the resulting complications.

The second case is an example of the rapid diffusion of something worthwhile, the computed tomography (CT) scanner. Since 1973, more than 1000 scanners have become operational in this country, with a capital cost of more than $500 million and annual operating costs also more than $500 million. In 1976, the Office of Technology Assessment estimated that CT scanning added $300 million to the national health bill (some of the cost was offset by reduced use of diagnostic procedures). As for the benefits, they remain largely unknown, although CT scanners certainly produce accurate images of pathological conditions such as brain tumors and can prevent diagnostic surgical procedures in the brain and abdomen. But the diffusion occurred with little reference to possible benefits. The numbers of scanners that are needed to serve the population appropriately, and the indications for scans, remain unknown. There clearly is a great deal of use of the head scanner, at least, in inappropriate situations, such as in people with headache but no other findings.

Another example of rapid diffusion and overuse without full evidence of benefit is coronary bypass surgery. The procedure was introduced in the early 1970's as a treatment for coronary artery disease, and an estimated 65,000 were done in 1976 at a cost of $650 million. There is some evidence of benefit in one clinical trial that showed improved survival in patients with narrowing of the left coronary artery—that is about 10 percent of patients being operated on. Operation for relief of pain of angina pectoris is controversial, but it is known that the placebo effect of such major surgery is considerable. The risk for major surgery is obvious.

Hysterectomy is an example of an established procedure with uncertain benefits or with overuse, depending on one's definition. In 1973, 690,000 hysterectomies were done, making it the most common major operation, with a cost of about $2 billion. Overuse is suggested by large variations in rates from region to region or from this country to other countries. It is often done because of fear of cancer or for contraception. The risks are about ½ percent death rate, postoperative infection, bleeding, and so forth, and some psychological risks that have not been well-studied. Despite the costs, risks, and uncertain benefits no clinical trial is underway to examine this procedure further.

Finally, an example of a technology that is widely used with little evidence of benefit: electronic fetal monitoring. With this procedure, the fetus is electronically monitored while the woman is in labor. External monitoring of the fetal heart rate can be done with ultrasound, but use of internal monitoring (with an electrode inserted into the scalp of the fetus) is increasing. In the latter type, it is also necessary to have a catheter in the uterus and to sample blood from the fetus in case of abnormalities in the heart rate. This procedure was initially used on high risk women but is increasingly recommended for all labors. At least half of all deliveries in this country are electronically monitored, and the costs are close to $100 million for the monitoring alone. In addition, the rate of Caesarean section rose from 5.5 percent of deliveries in 1965 to 12.8 percent in 1977, and fetal monitoring is an important cause of that rise. So the costs and risks of Caesarean also have to be considered. The benefits are really unknown. Many institutions have reported falls in perinatal (around the time of birth) mortality of infants after introduction of fetal monitoring, but these results have not been corrected for changing abortion laws, availability of contraception, better pre-natal care, and so forth. Two well-designed clinical trials in high risk women showed no benefit. Clearly the benefit is small enough that a very large clinical trial would be necessary to show benefit unequivocally. And there certainly is no evidence of benefit in the 85 to 90 percent of low risk or normal deliveries.

In presenting these cases, we have tried to illustrate a variety of problems concerning medical technologies. In several cases, it may have been preferable to delay diffusion until more was known about the benefits and costs of the technologies. The common thread in all the cases is the lack of available information on efficacy and safety. Obviously, these cases can be regarded as negative examples. We used them not to imply an indictment of all medical care but rather to show the seriousness and the importance of informed skepticism regarding efficacy and safety.

In our report on efficacy and safety, published in final form in 1978,[3] we examined seventeen cases of specific technologies and also reviewed the methodologic and policy-related literature on efficacy and safety. We analyzed the variety of methods available for demonstrating efficacy and safety. The field of technology evaluation is still maturing, so it needs considerable methodology development. Nonetheless, existing methods could be used more often and an expanded investment in scientific studies is justified. The most rigorous method of evaluation, of course, is the randomized controlled clinical trial.

Several Federal agencies support clinical trials, but the National Institutes of Health is by far the largest supporter. In 1975, NIH expended about 4 percent of its budget, $115 million, on 755 trials. Four percent seems intuitively small. The investment is also less than 0.1 percent of the national health expenditure. In addition to problems of the size of the effort, the priorities for evaluation could be criticized. 535 of those trials are of drugs, which are already effectively regulated through the Food and Drug Administration. Only 25 of them, however, were of surgical procedures, only 85 of diagnostic technologies, and there were very few of screening or preventive technologies.

In addition to studies themselves, we need summaries or syntheses of what's known. In the process of carrying out such syntheses, gaps in knowledge are identified and appropriate studies can then be carried out. Further, the government and often the professional societies themselves fail to do an adequate job of disseminating, in usable form, the information that does exist about efficacy and safety. In fairness, practitioners have not usually been active in letting government agencies such as NIH know instances where they feel the need for better information on benefits and risks.

Problems concerning efficacy and safety, then, included: 1) considerable gaps in knowledge of the appropriate indications, based on valid demonstration of benefits and risks, for use of technologies; 2) what appears to be quite a low level of resources devoted to controlled clinical trials, and a severely skewed distribution, of at least the governmental effort, toward cancer drugs and away from preventive, surgical and other technologies; and 3) inadequate synthesis and dissemination activities.

During 1977, as we worked on our report on efficacy and safety of medical technologies, Senator Kennedy had a number of public hearings concerning these problems. These hearings focused attention on the issue and began to produce a climate conducive to change. In June of that year, the new Assistant Secretary for Health, Dr. Julius Richmond, promised Senator Kennedy to develop a plan to address these problems. His Technology Management Task Force relied heavily on the OTA draft report on efficacy and safety in coming to its conclusion that a new program was needed in the Department of HEW. Subsequently, the Congress passed legislation establishing a new agency, the National Center for Health Care Technology.

This new National Center is designed to address many of the problems discussed above. It is authorized to conduct or support evaluations of medical technologies and their efficacy, safety, cost-effectiveness, and social implications. Evaluation of efficacy and safety is emerging as the most prominent of these areas. Importantly, the agency is charged with synthesizing and analyzing available information and with disseminating this synthesized knowledge to the government and other health care decisionmakers, including practitioners. It is not a regulatory agency; it sets no mandatory standards for use of a medical technology. It does, however, provide recommendations, when requested, to the Medicare program on whether specific technologies should be covered under Medicare. This agency gives the executive branch for the first time a focus for its myriad technology-related activities. The Center, with its national advisory council, can possibly develop into a receptive audience for practitioners and others concerned about medical technology—concerned both about the status of information on efficacy and safety and about their perceptions of the dangers or the opportunities for increased attention to assessment.

At OTA, we have not supported new regulatory programs, nor have we felt that any government action in this field could be successful without new knowledge about the benefits and risks of medical technologies. Furthermore, we have felt that it would be preferable if physicians became more conscious of problems of overuse and inappropriate use of medical technologies and addressed the problems without government interference. However, without better knowledge concerning medical technology, any efforts to change use of medical technologies seemed doomed to failure.

Public policy, of course, has multiple goals. One of the most important goals at the moment is cost-containment. We mentioned at the beginning of this discussion that medical technology has been seized upon as an issue in large part because of a perception that management of its effects may help constrain costs. It seems doubtful to us that a strategy focusing on medical technology can be in itself successful in controlling cost increases. The distribution of the costs can perhaps be changed significantly: increased information on appropriate uses may change the mix of technologies used in medical care. In other words, the quality of care would improve. That possibility invites, in fact requires, the active participation of health care practitioners.

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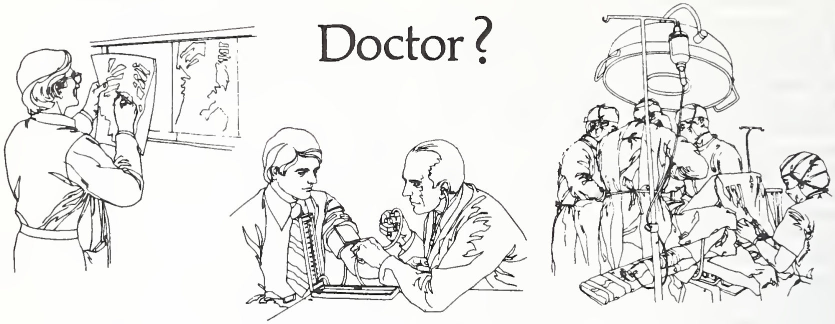

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The Modernization of Chinese Traditional Medicine

SUNG J. LIAO, M.D., D.P.H., F.A.C.P.

Under the current program of Four-Modernization in China, the emphasis of modernization of Chinese traditional medicine is evidenced by the National Symposia of Acupuncture and Moxibustion and Acupuncture Anesthesia held in June 1979 in Beijing (Peking).* I had the honor to be invited by the Ministry of Public Health and Chinese Medical Association to attend the meeting. The excellence of the research presented in that 5-day conference showed us what our Chinese colleagues could achieve in spite of the 10-years' great handicap of lack of modern research equipment and shortage of properly trained personnel.[1] Many of the participants are graduates of Xiangya (Hsiang Ya) Medical College and Hunan Medical College. (Incidentally, Hsiang Ya means Hunan-Yale and Hunan Medical College is its successor since World War II.) Thus, it is important at the outset for us to review briefly the history of Yale-China Association and its tremendous influence on China before we could discuss the modernization of Chinese traditional medicine in its proper perspective.

It started in 1914 when the late Dr. Edward Hume opened a clinic in Changsha, the capital city of Hunan Province, under the auspices of Yale-in-China Association as our Association was known in those days. Quickly Dr. Hume's fame spread. One day, the Provincial Governor's mother was gravely ill and dying in spite of the efforts of the best Chinese traditional physicians. In desperation, the Governor invited the foreign doctor in town to see if his Western medicine could possibly resurrect her from impending death. Dr. Hume saw the patient and told the Governor, "Your Excellency, if your honorable mother shall sweat profusely tonight and her temperature shall come down, she will recover by tomorrow." Indeed, she woke up the next morning bright as a daisy. (Dr. Hume diagnosed her illness as lobar pneumonia, which before the advent of antibiotics would by the 7th day either resolve by crisis with her recovery or terminate with her death. It was that fateful day when Dr. Hume saw her.) The Governor was so impressed that he asked Dr. Hume to teach the wondrous Western medicine to his people.

In 1919, the then Yale-in-China Association obtained a charter from the Connecticut General Assembly in Hartford to establish a Hsiang Ya Medical College and grant M.D. degrees in Changsha. Thus, the founding members of our Association helped to introduce Western medical education to China and laid at least part of the foundation of the current medical modernization there.

During my three visits to China since 1972, I found that many Hsiang Ya alumni are prominently participating in medical and health activities there. For example, among the graduates of the first class of Hsiang Ya are Dr. Zhang Xiaoqian (H.C. Chang) and Dr. Ying Yuanyao (Y.Y. Ying), both in their 80's now. Dr. Zhang is still active in teaching at Capital Hospital in Beijing as Chief of Medicine and is also Vice President of Chinese Academy of Medical Sciences. He took a year off to study Chinese traditional medicine. Dr. Ying is President of the Second Military Medical University in Shanghai. The Vice President of the same University, Dr. Xiang Qian, is also a Hsiang Ya man. The Commissioner of Public Health of Greater Beijing is Dr. Tan Zhuang, another Hsiang Ya man. Dr. Xiang and Dr. Tan went to Yenan in 1938 to join the late Chairman Mao Zedong and the late Premier Zhou Enlai. Dr. Chen Zhengren is the Director of Central Institute of Biological Products in Beijing which is also the main research laboratories for the

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Presented at Yale-China Association Symposia "China Tomorrow—Development of Medicine in China," September 14, 1979.

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*The Hanyu Pinyin System is used here for the Chinese words, followed by the familiar Wade-Giles System in parenthesis.

development of vaccines, antisera and antibiotics. Their products include Sabin polio vaccine and encephalitis vaccines among many others, supplying not only China but also the Third World countries. Dr. Chen Rongdian, a prominent surgeon in Zunyi, Guizhou (Kweichow) Province, experimented successfully in the use of herbal medicines to treat acute abdominal diseases. Dr. Lu Enci in Changsha is a surgical oncologist specializing in pancreatic tumors. Dr. Zhang Youhui of Peking is an associate professor at Chinese Academy of Medical Sciences specializing in cancer immunology. Dr. Hou Zonglian is a neurophysiologist at Xian (Sian) Medical College actively engaged in the research on acupuncture. Dr. Zhou Renxian (an internist) and Dr. Jiang Dashu (a neurologist) are on the faculty at Academy of Chinese Traditional Medicine in Beijing. Since there are so many Hsiang Ya graduates scattered all over China, I mention just the above few to illustrate their diversified activities in teaching and research and their possible roles in the modernization of Chinese traditional medicine.

Using modern chemical technology, Chinese researchers were able to find new uses of medicinal herbs. For example, they extracted a hypotensive agent from the herb, *Stephania tetrandra* S. Moore,[2] an antileukemic agent from plum yew (*Cephalotaxus fortunei* Hook f.),[3] an antiurinary-bladder-tumor agent from *Camptotheca acuminata* Decne,[4] and an agent from *Radix puerariae* for migraine headaches.[5] The male birth-control "pill," Gossypol, extracted from cottonseed oil,[6] was even reported recently in a newspaper here.[7] These purified chemical agents seemed to have rather little, if any, untoward side-effects on human beings. Among many other institutions, the Academy of Chinese Traditional Medicine and Institute of Materia Medica of Chinese Academy of Medical Sciences are actively engaged in exploring herbal pharmacology. Their synthesis of insulin at Shanghai Institute of Biochemistry in 1965 was totally unexpected by the Western scientific community.

Acupuncture has been much publicized in this country since 1970-71. Several years ago, it was considered a cult or unscientific folklore by American medical profession because we could not find any scientific equivalents of its basic theorems. The controversy was enhanced by entrepreneurs trying to commercialize it. The first indication of meaningful investigation by Chinese regarding the mechanism of acupuncture was shown in a movie made in Shanghai and first exhibited here in 1973[8] in which neuroanatomical basis was explained, and a cross-circulation experiment demonstrated transferability of its analgesic effects through the blood from an acupuncture-treated animal to one untreated. The second report available to the West was published in 1974.[9] It revealed that such analgesic effects could also be transferred from an acupuncture-treated animal to one untreated through transfusion of cerebrospinal fluid, with the involvement of certain neurotransmitters, such as catecholamines (particularly serotonin) and acetylcholine in its mechanism. Researchers in this country[10] and Canada[11] have expanded the investigation to implicate endorphins and enkephalins as the major analgesic agents released in the brain by acupuncture. During the afore-mentioned acupuncture symposia last June, we found that neurophysiologic and neuropharmacologic research of acupuncture had been initiated over 10 years ago in China. What is astonishing to the visitors from abroad is that they could have accomplished so much under such great difficulties during the culture-revolution days. The meeting was attended by about 500 medical researchers from all over China and about 125 foreign guests from 37 countries. The scientific presentations indicated enormous amounts of superb research work being conducted in this aspect of Chinese traditional medicine. The emphasis of medical modernization was further evidenced by a reception given by Chairman Hua Guofeng for symposia members. It was the first time that Chairman Hua did so at a medical meeting because of his interest in developing Chinese traditional medicine to the highest level.

At the Academy of Chinese Traditional Medicine in Beijing, for example, the President of Acupuncture Research Institute, Dr. Wang Xuetai, and the Director of Medicine of the Academy, Dr. Li Yunjie, were originally "Western physicians" (Xiyi) and learned acupuncture from the late Dr. Zhu Lian, also a Western-trained physician, who was Vice Minister of Public Health during the late 1940's. Her book, "New Acupuncture," was first published in 1951 and promptly translated into Russian by the Russian Academy of Medical Sciences. Needless to add, there are many other Western-trained physicians and medical researchers on the faculty at the Academy of Chinese Traditional Medicine.

In 1956, four Institutes of Chinese Traditional Medicine were established in Beijing, Shanghai, Guangzhou (Canton), and Chengdu (Chengtu). At the present time, the traditional medical curriculum consists of 70% Chinese traditional medicine and 30% Western medicine (especially basic medical sciences). While visiting the Guangzhou Institute, I accidently witnessed a traditional physician using a stethoscope and reflex-hammer during the physical examination of a patient. I found his technique entirely the same as ours. At that Institute, there are a clinical laboratory, an ECG laboratory and a X-ray department, among other diagnostic facilities. Previously, such Western provisions in a traditional environment would be considered heresy. During my visits, my hosts and friends often expressed a welcome for educational and technical exchanges with our medical and health professionals to expedite their efforts and to bring their traditional medicine to the highest modern standards.

In conclusion, I was especially impressed at the acupuncture symposia last June that Chinese Western-trained physicians, (Xiyi) and traditionally-trained physicians (Zhongyi) are working closely together with modern scientific technology to explore and to systematize their traditional medicine and herbology so as to forge a new Chinese medicine and pharmacology as a part of their Four-Modernization movement. They are anxious to learn our American medical technology and welcome culture exchanges with our professionals.

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LIFE & CASUALTY

The Automobile Insurance Company of Hartford, Connecticut

New Britain General Hospital
vs.
Commission on Hospitals and Health Care

DECISION OF THE SUPERIOR COURT
HARTFORD JUDICIAL DISTRICT
December 26, 1979

Memorandum of Decision

Preliminary Statement: This is an appeal from a decision of the Commission on Hospitals and Health Care denying the New Britain General Hospital's application to expend $644,750.00 for the purchase and installation of a CT whole body scanner.

On January 8, 1979, the New Britain General Hospital, a "health care facility or institution" within the meaning of Conn. Gen. Stat.,[1] . . . filed an application as required by Conn. Gen. Stat.,[2] . . . seeking approval of a $644,750.00 expenditure for a computerized tomographic whole body scanner.

On May 7 and May 11, 1979 a panel of three commission members conducted a public hearing concerning New Britain General Hospital's application. On June 6, 1979 the hearing panel issued a proposal for decision denying the application and assigned June 12, 1979 as the date for presentation of the application to the full commission. On June 12, 1979, the full 14 member commission approved the panel's report and denied the hospital's application. On June 20, 1979, New Britain General Hospital served notice of its appeal of that decision to this court.

Jurisdiction: [Authorized by statute]

Statutory Requirements: Computed Tomography (CT) is an X-ray procedure which utilizes a computer and a television screen to create cross-sectional images of internal structures and organs which are technically superior to conventional x-ray pictures. The procedure is nontraumatic and painless for the patient. CT scanning has been a rapidly developing technique. Cost of full body scanning equipment can be as high as $775,000.00 while equipment limited to headscanning can cost as little as $96,500.00. On weighing an applicant's request for a capital appropriation of the magnitude of a full body scanner, the commission is confronted by statute with the Augean task of assessing a variety of specific factors in making its decision. These include the necessary expenses of the institution concerned, its teaching and research expenses, its community service programs, comments received from Professional Standards Review Organizations regarding its volume, the need for preservation of capital and segregation of grants, its patient mix, the growth of its patient load, its accounts receivable experience, the effectiveness of its delivery of health care services, the quality of available health care, *the duplication of service by institutions and facilities in the area served, the community or regional need for any particular function or service,* and any other factors which the commission deems relevant, . . . Further, the commission must also consider *"the availability of such service or function at other health care facilities or institutions* . . . within the area to be served . . . (and) *the need for such service or function within such area.* . . . Finally, the commission must assess the application in relation *to* the *community or regional need for such* capital program, the possible effect on the operating costs of the health care facility or institution, (and) the recommendations of the Health Systems Agency regarding such proposal. . . ."

EDITOR'S NOTE: Legal references are omitted. These can be obtained by writing The Connecticut Hospital Association, 10 Alexander Drive, Wallingford, CT 06492.

Area, Community, Region: In processing its application, New Britain General Hospital perceived that it was dealing with a geographical area that included patients from New Britain, Berlin, Plainville, Southington, Bristol, Middletown and portions of Newington, Farmington, Plymouth, Meriden, Cromwell, Burlington, Wolcott, Cheshire and Middlefield. The estimated population within this service area was 297,300. In formulating its decision on the issue of the need for the full body scanner, the commission adopted the same geographical area. Having done so, the commission thereafter concluded there was no need for such equipment within this area. The decision then continued with a discussion of the use by New Britain patients of the full body CT scanner at St. Francis Hospital. This facility is in Hartford and is clearly outside of the service area contemplated by the application and addressed by the commission in concluding that no need existed for the proposed equipment. If this discussion about St. Francis Hospital's full body scanner was intended to address the issue of "the availability of such service . . . within the area to be served . . ." required by Conn. Gen. Stat. . . . then the commission has inexplicably changed the parameter of the service area then in question. If the remarks were not intended as such, then it appears that the decision has not addressed this issue at all, contrary to the statutory requirement.

In addition to the matter of the "area to be served", Conn. Gen. Stat. . . . directs that the commission evalue ". . . the *community or regional* need for any particular function. . . ." The statement appears directly after a requirement that the commission consider "the duplication of service by institutions and facilities in *the area served."* The words "community" or "regional" mean something other than "the area served." If not, one of the phrases would be superfluous and the phrase could simply read "the duplication of service by institutions and facilities, and need in the area served," or "the duplication of service by institutions and facilities and need in the community or region." "It is commonplace that (n)o word in a statute should be treated as superfluous, void or insignificant unless there are impelling reasons . . . why this principle cannot be followed. . . ."

Although the commission attempts to address this issue by concluding that "there is no regional or community need for a full body CT scanner at the hospital . . .", the only material in the decision about scanning-needs discusses the situation within the New Britain General Hospital service area. There are no underlying facts found by the commission as to what the community or regional needs may be to support the conclusion that no community or regional need exists. Conn. Gen. Stat. . . . requires a consideration of need which goes beyond the parameters of the applicant's service area.

Duplication of Service: Conn. Gen. Stat. . . . further requires that the commission consider "the duplication of service by institutions and facilities *in the area served. . . ."* The commission specifically considered the issue, identified the apparent service area, and then concluded that there would be a duplication of services with the full body scanner at St. Francis Hospital in Hartford. Again, the commission has either inexplicably changed the parameters of the service area it is discussing or has failed to directly consider the issue required by the statute, i.e. "duplication of service . . . *in the area served. . . ."*

Conclusion: Based on all of the foregoing, the court concludes that 1) the commission has not addressed the community or regional need for a full body CT scanner as required by Conn. Gen. Stat. . . . as there has been no factual finding as to what the community or regional need may be; 2) the commission has not addressed the matter of duplication of service . . . *in the area served* as required by Conn. Gen. Stat. . . . nor the matter of "the availability of such service . . . *within the area to be served* as required by Conn. Gen. Stat. . . . 3) to the extent that the decision may be undertaking to deal with these statutory considerations, the terms "area served", "community" and "region" have not been defined with adequate particularity to enable the parties or a reviewing authority to determine whether the decision may be fairly supported by the record.

In view of the significant cost of the whole body CT scanner, the fact that regional placement and sharing of such equipment may be in order and effected by the decision here, and in view of the fact that other area hospitals are also considering the installation of full body scanners, a reversal of the commission's decision and a granting by the court of the plaintiff's application could represent an injustice of a magnitude far outweighing the apparent irregularities in the commission's decision. The matter is therefore remanded to the commission for its further hearing, deliberation, finding and decision on the plaintiff's application in accordance with this decision. There are no costs taxed to any party.

Court of Common Pleas
Judge Alfred Covello

REFERENCES

1. *Conn. Gen. Stat. . . . Definition.* "As used in this chapter . . . 'health care facility or institution' means any facility or institution engaged primarily in providing services for the prevention, diagnosis and treatment of human health conditions, including, . . . hospitals; . . ."
2. *Conn. Gen. Stat. . . . Requests for approval of capital expenditures of one hundred thousand dollars or more.* (a) Any health care facility or institution . . . proposing a capital expenditure of one hundred thousand dollars or more . . . shall submit a request for approval of such expenditure to the commission . . ."

Medicare Benefits (EOMB) Form

AMA COUNCIL ON MEDICAL SERVICE

At the 1979 Annual Meeting, the House of Delegates asked that the AMA make the public aware of Medicare misrepresentation of the rate at which physical services are reimbursed, that the misrepresentation be investigated, and that the AMA seek an addendum to the Explanation of Medicare Benefits (EOMB) form in regard to the relation of Medicare payments to actual prevailing charges, and attempt to correct Medicare misrepresentation of payment rates.

The Council on Medical Service is calling for an addendum to the EOMB form, through discussions with Medicare officials, and submits this report on these discussions for the information of the House.

The Medicare program, in most cases, pays for covered physicians' services under the Part B (Supplementary Medical Insurance) program on the basis of what the program determines to be the "reasonable charge" for the service. Since the law was enacted in 1965, the formula by which a carrier determines the "reasonable charge" has become more uniform nationwide, through increasing specificity in both the law and in regulations and directives to carriers.

The formula has also become more complex, to the degree that the Council on Medical Service last year published a brochure on "Physician Fees Under Medicare" to help physicians understand the process by which Medicare fee screens are established.

The Council does not intend to replicate that brochure here, but believes a brief discussion is essential to understanding the problems with the EOMB form.

In most cases, the Medicare "reasonable charge" will be the *lowest* of four charges:

(a) the individual physician's actual charge for the service;
(b) his customary charge for the service;
(c) the prevailing charge for the service; or
(d) the amount the carrier pays on its private policies.

The "customary charge" and the "prevailing charge" are determined by the carrier on the basis of charge data from the calendar year prior to the July-June "fee screen year" in which a claim is submitted. Thus Medicare payment for any claim submitted from July 1979 through June 1980 is based on charge data from 1978.

In this context, the Medicare "customary charge" for an individual is defined as the dollar amount which would cover his charge at least half the time during the calendar year. (Example: If he charged \$10 ten times, \$15 ten times, and \$20 ten times, \$15 would be his "customary" charge.)

The Medicare "prevailing charge" is the 75th percentile of "customary" charges for the service in the area, by physicians of similar training and experience, weighted by the frequency with which they performed the service. (Example: Doctor A performs service X 10 times at a \$10 customary service, Dr. B 50 times at \$15, Dr. C 25 times at \$20, and Dr. D 15 times at \$25; the prevailing charge is \$20—the customary charge which would cover 75 percent of the services.) The prevailing charge is further restrained by the "economic index" which limits its annual percentage rise.

The EOMB problem, obviously, is the difficulty in explaining to the beneficiary why the "reasonable charge" amount, of which Medicare pays 80%, may be less than the physician's actual charge. Various standard phrases were tried during the program's early years, such as "More than the reasonable charge" and "More than the allowable charge." Both created friction between patient and physician, because of patient misunderstanding of the real meaning of the terms within the Medicare law.

Currently, therefore, the EOMB form contains, on the reverse, a fairly detailed explanation:

> "The amount Medicare may pay under law is limited to the lowest of:
>
> a. Customary charge, i.e., the charge made by the physician or supplier in 50% of his billings during the base year;

EDITOR'S NOTE: This is a report of the AMA Council on Medical Service to the House of Delegates at its meeting in December 1979.

b. Prevailing charge, i.e., the charge made 75% of the time by other physicians or suppliers for similar services in the area during the base year."

This language is not a complete or accurate statement of the Medicare reimbursement limitations; it oversimplifies the customary charge "median" and the prevailing charge "75th percentile," does not define the "base year," and omits the "economic index." However, it is a substantial improvement over identifying a physician's actual charge as "more than reasonable" or "more than allowed," and the "base year" mention at least implies that the charge is not a current one.

This last point was addressed at the last meeting which asked the Association to seek an addendum to the EOMB form to explain that Medicare payments "do not necessarily reflect actual, prevailing charges in the patient's local area."

New Draft EOMB Form: In May 1979, the Council received a draft proposal from Medicare for a revised EOMB form. Along with a number of other changes, which substantially increase the amount of information the form could convey to beneficiaries, new wording explaining the limit on Medicare payment was proposed, stating that the amount Medicare may approve as the "reasonable charge" is determined by Medicare law and regulations, and that:

"The 'reasonable charge' for a particular service is the lowest of the following physician/supplier charges:

a. The actual charge to you;
b. The amount usually charged to his patients;
c. The amount usually charged by other physicians in your community; or
d. An amount that is no greater than a nationally allowed increase resulting from inflationary trends over last year's usual community charges."

The Council has pointed out by written communication and in meetings with Medicare officials that the language now in use on the EOMB form, though deficient, is both more accurate and more complete than the proposed new language, which omits all reference to the median in defining the customary charge and all reference to the 75th percentile in describing prevailing charges, as well as any reference to the fact that neither charge screen is current.

The Council has further pointed out that misleading statements on the EOMB form have in the past led to beneficiary misunderstanding and physician-patient friction, and has strongly urged that the language be revised to provide a more accurate description of the Medicare reimbursement limitations, including the addendum called for by Resolution 34. The Council has been informed by Medicare officials that the draft EOMB form is being revised in the light of the Council's comments, and will be tested with beneficiaries before being finalized.

According to latest reports, no final revision of the EOMB form will be in general use before spring 1980. The Council will continue to seek more accurate language in its meetings with federal officials and through correspondence, and will advise the House of any changes in the situation.

The AMA and the Public

The credibility rating of the American Medical Association with the public "continues high," according to a study completed in December, 1979 by the Gallup organization. The rating was slightly down from a similar 1976 study.

The AMA posted a 6.8 mark, based on a scale of 1-10, with only the American Dental Association ahead with a rating of 6.9.

Other ratings included the American Bar Association, 6.1 . . . National Rifle Association, 6.6 . . . American Hospital Association, 5.8 . . .Pharmaceutical Manufacturers' Association, 5.8 . . . American Trucking Association, 5.8 . . . National Association of Manufacturers, 5.7 . . . National Association of Realtors, 5.1 . . . American Petroleum Institute, 3.7. The study also developed ratings for the news media, 6.0 . . . Business corporations, 5.1 . . . Labor unions, 5.2 . . . and federal agencies, 5.9.

Month in Washington

Congressional appropriations committees are considering the Administration's proposals for a further $500 million reduction in health program funding.

The cuts in an already Spartan health budget, made as part of President Carter's all-out drive to balance the budget to fight inflation, normally would receive short shrift in Congress where health usually is treated generously. However, this year promises to be different as Congress generally shares the Administration's concern about budget deficits.

In addition to the cuts for the fiscal year 1981 starting next October, the Administration is seeking reductions in appropriations for the current year and rescissions of appropriations already approved by Congress. Congress was asked to delay action on the $300 million Child Health Assurance Program, originally slated to take effect next fiscal year, and on legislation expanding Medicare and Medicaid benefits. There was even a six-month postponement, until 1983, of the Administration's National Health Insurance plan.

There was little policy evident in the indiscriminate, down-the-line budget paring of health programs. Disease prevention, mental health, alcoholism, and the National Health Service Corps, not to mention the Child Health Assurance Program had all been Administration favorites.

Proposed Health, Education and Welfare cuts are as follows:

Health Services Administration—cut by $117 million, including $47 million for the National Health Service Corps, $21 million for community health centers, and $15 million for family planning.

Center for Disease Control—cut by $98 million, led by $52 million for health incentive grants.

National Institutes of Health—cut by $91 million plus another $41 million from this year's appropriation.

National Cancer Institute—cut by $43 million.

National Heart, Blood and Lung Institute—cut by $15.6 million.

Alcohol, Drug Abuse and Mental Health Administration—cut by $102 million for state formula grants.

Health Resources Administration—cut by $73 million including $38 million for local health planning.

The AMA has told the Congress that "In these times of escalating costs and growing demands for increased federal financial support in governmental programs, it is more important than ever that the Congress provide the leadership necessary to establish priorities for the expenditures of finite federal funds."

In testimony before a subcommittee of the House Committee on Appropriations, the AMA warned that it was essential that all sectors of the economy cooperate.

"In this connection the medical profession has undertaken an examination of all aspects of health care delivery in order to constrain rising costs and conserve the public and private health care dollar without sacrificing the quality or availability of health care services," the AMA said. "Through the 'Voluntary Effort' the medical profession and other organizations have created an affirmative and positive program demonstrating the concern of the private sector in controlling hospital expenditures and seeking to ameliorate the impact of inflation on health care costs. This program has proven itself effective. Physicians, too, in response to an AMA call for moderated increases in physician fees, have responded effectively, with physician fee increases being below the 'all items' portion of the Consumer Price Index for the past two years."

In conclusion, the AMA testified that "While we recognize that governmental priorities must be established and that certain programs must be cut, we believe that other programs, including those we have discussed with you, should be strongly supported if the health needs of the American people are to be met. We urge this Committee to consider carefully any reductions in federal funding that might compromise the health of the American people."

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The AMA has said no to a federal proposal that physicians be asked to limit their fee increases to 6.5 percent this year. AMA Executive Vice President James H. Sammons, M.D., has told government officials that the overall rate of inflation is running at about 18 percent and that Wage Guideline limits have been set at from 7.5 percent to 9 percent.

The Health and Human Services Department (the new name for the old HEW Department) and the Council on Wage and Price Stability (COWPS) have been meeting with leaders of the health providers in an attempt to set voluntary fee and price limits.

Prepared by the Washington, D.C.
Office of the American Medical Association

Dr. Sammons said the AMA will continue to urge individual physicians to exercise restraint, a policy that has resulted over the past two years in a rate of increase well behind the Consumer Price Index for the rest of the economy. In 1978 the CPI was 9 percent; physicians' fee increases, 8.1 percent. Last year the figures were 13.3 percent and 9.4 percent, respectively.

The talks with the private sector organizations making up the VE mark a distinct change in official attitude. Former HEW Secretary Joseph Califano did not recognize the VE as a legitimate effort to hold down inflation and made it the subject of snide attacks. The present Secretary Patricia Harris has inaugurated a policy of working with the private sector and refraining from name-calling.

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The Administration has told Congress there will be plenty of physicians around in the 1980s. The bright outlook on the physician supply happens to coincide with the Administration's desire to slash funding for medical education. Hearings are underway in Congress on extending the medical manpower laws.

The report to Congress said the number of active United States physicians increased more than 17 percent from 323,000 in 1970 to 379,000 in 1978. The "new" publication, a report to the President and Congress on the Status of Health Professions Personnel in the United States (1980), also cited increases during the period in the numbers of active practitioners in other health professions: Dentistry up 19 percent from 102,000 to 121,000; Optometrists, 15 percent, from 18,400 to 21,200; Pharmacists 23 percent from 109,600 to 134,600; Podiatrists, 14 percent, from 7,100 to 8,100; and Veterinarians, 32 percent, from 25,000 to 34,200.

The HEW Department which issued a similar report last year, said projections for the 1980s indicate that the supply of physicians "probably will be adequate to meet the nation's needs and could actually exceed requirements. By 1990 physician requirements are predicted to range from 553,000 to 596,000 compared to an anticipated supply of 600,000."

The report points out that the projected increase in physician supply does not solve geographic distribution problems.

"To solve geographic inequities will require some leeway in the supply to encourage potentially excess health personnel to locate in areas that would not otherwise get the manpower required," according to the report.

The report also said the anticipated increase in the supply of U.S.-trained physicians should lessen a previous reliance on Foreign Medical Graduates who accounted for 11 percent of physicians in 1963 and 20 percent in 1977.

There have been substantial increases in the numbers of women and minority students pursuing health careers, but there is no health profession in which the percentage of practitioners or the level of enrollment of minorities and women is equal to their representation in the civilian population, according to the report.

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The AMA has opposed as unnecessary a pending bill in the House titled the "Privacy of Medical Information Act" (HR 5935).

Appearing before Ways and Means subcommittee on Health, spokesman Frederick W. Ackerman, M.D., Chairman of the AMA Council on Legislation, said that while the Association shared with the Congress its deep concerns over increasing threats to the confidentiality of medical records and the erosion of privacy of patients, it was seeking appropriate state legislative solutions to the problems, while at the same time working to educate physicians and others to be sensitive to these issues.

"Basic to our objection to enactment of the bill is our view that there is no need for comprehensive federal legislation," Dr. Ackerman said. "Any deficiencies in the present system relating to confidentiality of medical records do not justify enactment of federal legislation with the morass of regulation assuredly to follow.

"We believe that the states have shown an increased willingness and ability to respond to these problems. Congress should encourage these activities, not supplant them. Accordingly, we urge the Congress not to adopt comprehensive federal legislation, but to limit its activities to appropriate federal areas in which the states cannot act."

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Legislation in another area to protect medical peer review records maintained by the Veterans' Administration from public release was backed, however, by the AMA. Confidentiality is critical to the success of any peer review program, the AMA said in support of an amendment of Sen. Herman Talmadge (D-GA) to the VA Physicians Pay bill (S.2534).

The AMA noted it has consistently supported congressional efforts in assuring the confidentiality of records of Professional Standards Review Organizations.

Reflections from the Dean's Office

Can Regulators Be Regulated?

ROBERT U. MASSEY, M.D.

During a meeting with regulators over a certificate of need application for a piece of equipment for the University Hospital, the conversation became animated, as it often does in these encounters. While both sides were seeking common ground, one regulator exclaimed, "I feel like a hostage! You're making it terribly difficult for regulators to be creative."

Our side responded that regulators are not supposed to be creative, and by definition cannot be creative. Someone said something about there being insufficient time for philosophical questions and suggested we move on to safer ground.

I suspect we were touching the nerve of an issue. People who regulate have a notion of where the world should be and believe that it can be got there by regulation. Theirs is the vision of an orderly world made up of policies, guidelines, and regulations in which, by denials imposed at the right times, society is reformed to the ideal. Plato's republic would have had regulators. The problem is that ideal societies have had a bad habit of turning into tyrannies with regulator-kings instead of philosopher-kings. Calvin's Geneva, Cromwell's England, and Lenin's Russia are examples of someone's honest idealism gone bad. Control by regulation is not the same as rule by law.

A good tyranny might be the best kind of state if one's own values coincide with those of the prince. *Cuius regio, eius religio.* Not everyone would be content in a society founded upon John Stuart Mill's principles of liberty, but that quite likely would be the most "creative" society, one in which, if progress toward good is either possible or a valid concept, the highest good can be attained. "Mankind are greater gainers by suffering each other to live as seems good to themselves, than by compelling each to live as seems good to the rest."[1]

It seems as though our Republic has held to that longer than anyone's republic. That sounds parochial, and I should object if I were an Englishman, a Dutchman, or a Swiss. The adherence to the principles of liberty in these places has been associated with creativity not usually seen in tyrannies. The problem is not that simple; there were liberties in Imperial Russia and Imperial Germany which did not flourish in Winesburg, Ohio.

For many reasons, we have come to accept increasing regulation in the matter of medical services to control costs, to improve access, and to affect distribution. At national meetings and local luncheons, speakers proclaim the facts of life: regulations are here to stay and will surely increase. This seems to be a tacit admission that regulations work, or that, like crime, they are ineradicable. There is often little evidence of their effectiveness. What can be shown is that regulations cost money and provide employment; that they are cost-effective is an unproved assumption. That they tend to grow along with their accompanying bureaucracy into every nook and crevice of society is demonstrable from history. That regulated societies tend toward tyranny, with everyone sliding along without noticing or else saying that it is all so inevitable, seems to be so.

Some regulation is necessary—luncheon speakers usually say that before going on to tell us that more is inevitable.

That is where we should shout "stop." There must be some law that the political scientists have invented that can be used to judge whether a regulation is useful. The eradication of smallpox owes as much to regulators—medical police—as to physicians, but just as we need technology assessment, so do we need regulation assessment.

There is a growing sentiment against regulation; our business colleagues are ahead of us in making their case. Later in his essay, Mill writes, "Speaking generally, there is no one so fit to conduct any business, or to determine how or by whom it shall be conducted, as those who are personnally interested in it." And on the following page, " . . . the most cogent reason for restricting the interference of government is the great evil of adding unnecessarily to its power."

Before anyone proposes another guideline or another commission, we might just recognize that the most dangerous regulation is one which favors our interest.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

REFERENCES

1. Mill, John Stuart: *On Liberty*, 1859.

The President's Page

The Connecticut State Medical Society has, at present, a combined Resident, Intern and Student membership of 513 from a potential three times as many. These few have joined in spite of having essentially no influence in the Society. Attempts to expand membership at the county level have not been successful due, in part, to the transiency of these young people and, in part, to the fact that we have little to offer them.

The House of Delegates is now considering by-law changes which would increase student-resident participation. Proposed changes are patterned after the very successful student and resident sections of the AMA, and would provide for representation from student and resident sections in addition to the present eight counties. These sections would elect representation to the House of Delegates as the counties do, but according to a diluted formula.

This proposal merits the support of all of the Society. We need these young professionals. Participation in, and knowledge of, organized medicine means increased membership and stronger societies in the future. Many of our leadership start so late in life that the Society cannot receive the full benefit of their years of preparation. Early integration of the younger physician into the Society would lead to early recognition and training of potential leaders.

Medical students and residents are chosen from the top of their college classes. Many have advanced degrees and many have backgrounds in the social sciences which enable them to bring new knowledge and ideas to the Society. Our democratic processes certainly lead us to expect that the best of these will be adopted and will render our society more vigorous and more appropriate to the times. We can expect to find as broad a spectrum of political and social philosophies in the student population as exists among ourselves.

We are frequently amazed to find how uninformed a large percentage of our physician population is in matters of political medicine and particularly of the nature, history and political roles of organized medicine. How often we hear unjustified criticism from the uninformed concerning the operation of our societies. Participation is an effective means of education, and should lead to a new generation of better informed physicians whose early involvement and positive experiences will lead them to identify with organized medicine and, therefore, participate to a greater degree. Education of the young physician in political matters has to be the prime objective of the by-law's revision. If we are successful, perhaps a few more teachers might be tempted to follow their students into the Society, giving us a foothold we so badly need in the academic world.

The future of organized medicine is now in the medical schools and training programs. Let us hope to develop new generations who will guarantee the growth of a strong and effective Medical Society.

W. Raymond James, M.D.
President

Inaugural Address of the Incoming President

W. RAYMOND JAMES

It is difficult to understand the tendency of so many of our profession to shy away from participating in organized medicine. As proud as we are of our own accomplishments—we should be equally proud to be a part of the medical societies that have so influenced the development of our profession. I am proud to be a member of this great Society. I am honored to have been elected your president. I hope that your faith in me will prove justified. I shall try to continue the fine traditions of this office set by my predecessors.

Recently, I came upon a bull session in the hospital. Discussion concerned the most desirable role one might choose if reincarnated. Consideration of all things from kingships to sainthoods faded when indoor plumbing, disease and individual freedom were considered. The consensus developed that living in this country at this time is the best of known existences. The conversation then shifted to the practice of medicine. It was generally agreed that ours is one of the most learned and perhaps the most esteemed of the professions and that American medical education, medical research and medical care are probably the best in the world. If this is really so, why then are we and our health care system being so vigorously attacked? We don't really know the answer. We do know that, even if we have the best of worlds, we are still presented with many problems which must be solved. Too many people have inadequate resources to provide themselves with necessary medical care. Too many have not or cannot provide for major medical expenses. The costs of medical care are rising too rapidly; there is maldistribution of medical care facilities and physicians; there is a lag between new knowledge and technology and their application; medicine is being eroded by inadequately prepared practitioners.

Basic as these problems are, they are small when compared to the need for adequate health education. A simple understanding by all persons of disease and of the availability of appropriate care is the single most necessary requirement for improvement of our health care delivery system and the public health. The billions of dollars now spent by government in efforts to modify the American system would be enormously more fruitful if diverted to this purpose.

We are blessed to be living in a period of unequaled social and scientific progress marred, unfortunately, by barbarism unmatched in recorded history. Medical practice today is as different from that of a century ago as is space travel from the horse and buggy. American frontiers have changed from the development of western lands to problems of social justice and economic stability. Pressures created by accelerating technology and social change will continue and increase. The greatest threat to American medicine, in this time of change, comes from persons in medicine and in government who genuinely believe that government can care for the individual better than the individual himself.

This "big brother" philosophy, or collectivism or whatever it is labeled, pervades all areas of our society. It is diametrically opposed to democracy based on individualism. Let us not forget that collectivism was the basic philosophy of the barbarisms which devastated Europe in the first half of this century. We find it in some proposals for national health insurance, in the National Health Planning Act, and in many of the regulations and laws that have come to be such a burden to us and to our patients. Our problem is not to resist change, as some have tried, but to show that we can improve health delivery, adopt technological advances, and adapt to social and political changes, while preserving our traditions of individualism and freedom. This we must do.

There is no escaping the necessity for coping with these problems. However, we must not allow our concern over social and political issues to divert us from our real role as physicians and as a society of physicians. The number one problem facing us today is not that of government interference, nor is it the inadequacies of the health care delivery system. Our number one problem is the conquering of blood vessel disease. More than half of all deaths, as well as untold suffering and disability, are attributable to this disease. Close behind in our priorities should be the prevention of cancer—responsible for nearly one-fourth of all deaths—and the control of senility, perhaps the most tragic of diseases. Solutions to these and other diseases will most quickly come from the concerted efforts of researcher, teacher and practitioner working unfettered in a free society.

Answers to none of our problems are obvious or simple, nor is it clear how much and by what means we can direct our future. One thing is certain, however, the illustrious past record of organized medicine in developing the high standards of education, practice and research that have brought us to our present enviable position can only be maintained if we have strong and effective medical societies.

To do this we must continue to develop resources within our societies so that we can provide expertise and information giving credence and support to our positions and actions, and so that we will be sought out by persons and agencies seeking information and guidance in matters related to health care and medical science.

We must improve our public image, for influence is determined by the public's confidence and respect. We will be measured not only by what we do—and this means raising the standards of practice and physician-patient relationships—but also by the image we can project of ourselves and our Society.

We must involve more physicians in our Society. Strength comes not only from greater numbers, but also from a Society that the public perceives as representing all of our profession. We must find ways of incorporating the research, the academic and the future physician into our Society.

I shall do my best this year to help improve our health care delivery system, to promote health education and medical research, to strengthen this Society and, most of all, to preserve our American system of health care.

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SUMMARY OF PROCEEDINGS
HOUSE OF DELEGATES—ANNUAL MEETING
Hartford, Connecticut—May 2, 1979

Reports and Addresses

The House received reports, addresses and/or remarks from the President, the Secretary, the Treasurer, the Council, Delegates to AMA, Standing Committees, Representatives and Advisors, the President of the Auxiliary to CSMA, Chairman of Board of Directors of COMPAC and the delegates from the medical societies in Massachusetts, New Hampshire, New Jersey, Rhode Island and Vermont.

At the Annual Dinner of the Society, the incoming President, W. Raymond James, Essex, made his inaugural address which is published in this issue on page 393.

Election of Officers and Others

With minor amendments, the House voted to approve the published report of the Nominating Committee (the Council). Officers elected were:

President: W. Raymond James, Essex
President-Elect: Andrew J. Canzonetti, Waterbury
Vice-President: Gioacchino Parrella, Milford
Secretary: Louis C. Backhus, Waterbury
Treasurer: John J. Mendillo, New Haven
Speaker of the House of Delegates:
  Joseph S. Sadowski, Hartford
Vice Speaker: Edmund H. Hecklau, Greenwich
AMA Delegates: Guy W. Van Syckle, Danbury
  Frank K. Abbot, Hartford
Alternate AMA Delegates:
  William A. Whalen, Jr., Willimantic
  Stewart J. Petrie, Derby
Councilor-at-Large:
  Edward A. Kamens, Fairfield

Presentations and Awards

Presentation to Retiring President: In recognition of his efforts as President of the Society during 1979-80, Edward A. Kamens, Fairfield, received a gift and past President's pin. The presentations were made by Andrew J. Canzonetti, Waterbury, Chairman of the Council.

Presentation to Incoming President: A plaque with a gavel, symbolic of the office of President of the Society, was presented to W. Raymond James, Essex, by the retiring President, Edward A. Kamens, Fairfield.

AMA-ERF Grants to Medical Schools: Provided by the AMA Education and Research Foundation, unrestricted grants were awarded as follows: To the Yale University School of Medicine—$3,727.00. Accepting for Yale was Howard Levitin, Associate Dean; to the UConn School of Medicine—$825.00. Accepting for UConn School of Medicine was Robert U. Massey, Dean.

Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House were heard by Reference Committees and based on the reports of the Reference Committee, were acted on as follows:

1) **Public Information Program:** VOTED to refer to the Committee on Public Relations for continued study the subject of a Public Information Program, as to the direction it should take, with a view of establishing priorities and specific recommendations concerning implementation of the program and to report back to the Council their deliberations for approval and that a report on this program be presented to the House of Delegates at its next meeting.

2) **Elderly Health Screening Program:** VOTED to reconsider the action on the subject taken at the meeting on November 15, 1979, and to approve of the following substitute policy statement:

SUBJECT: REPORT ON RESOLUTION ON ELDERLY HEALTH SCREENING

1. That the multiphasic screening program of this group, the Elderly Health Screening Program, has much to recommend it. However, the Ad Hoc Committee was very concerned about the way in which the information was dispensed and the professional liability of the practitioner to whom such patients and data were referred. It was the feeling of the Ad Hoc Committee that the Council should recommend to the House of Delegates that it reconsider its action on the subject and that the following points should be stressed to the Elderly Health Screening Council.

   a. That it is the responsibility of the individual person who seeks the service of this elderly health screening program to secure the data and to implement the recommendations of the screening group.

b. That the screening group is under the obligation to see to it that those persons seeking its services shall be properly notified as to the results of such screening in one of the following ways:
   1. That the individual has abnormalities.
   2. That no abnormalities were found.

c. In the case where abnormalities were found, it would then be the responsibility of the screening group to provide the individual with the documentation and recommend to the person that they seek medical attention. It is then the responsibility of the individual person to seek medical attention bearing the data with him.

   That it not be the practice of the screening group to send to the physician the results of the screening examination or the screening material.

d. In the case where no abnormalities were found, the individual should be notified of that fact, and also be informed that this screening was not to be considered a complete physicial examination. (It might be pointed out that we understand that this is the policy of the screening group.)

It was further VOTED that the Committee on Public Health be charged to have an ongoing concern and interest in multiphasic screening and, also, that all screening programs be strongly urged to secure physician input into the program both in the planning and execution phases of the program.

3) **Cost Benefit and Medical Care:** VOTED to approve of the following policy statement and forward to AMA:

The Judicial Committee of the CSMS expects that physicians will continue to be dedicated to providing the most appropriate treatment to patients, regardless of age, race, social or economic status, or their purported "value to society."

The medical profession will continue to resist any system which places cost considerations before the patient's own best interest.

It is expected that each physician will seek for each and every patient under his or her care the very best possible modality of diagnosis and/or treatment within that physician's power to provide, consonant with the state of the art and with the medical indications as understood at the moment.

4) **Medicare-Medicaid Program:** VOTED to adopt a resolution, the resolved portion of which follows:

RESOLVED:

That the Connecticut State Medical Society convey to Connecticut's state and federal legislators that it favors the same current procedural terminology and parity in reimbursement levels and practices for medicaid patients as for medicare patients.

5) **Revision of AMA Principles of Medical Ethics:** VOTED to adopt the following revision of the proposed Code of Ethics:

Preamble. These principles are intended to aid physicians individually and collectively in maintaining a high level of ethical conduct. They are not laws, but standards by which physicians may determine the propriety of their conduct in their relationship with patients, with colleagues, with members of allied professions, and with the public.

1. Physicians shall be dedicated to practicing their profession competently, compassionately, with kindness and respect for the dignity of each human being whom they serve.
2. Physicans shall uphold the honor of their profession, and shall fulfill its obligations to society by always dealing honestly with their colleagues and their patients, and by their willingness to expose those physicians deficient in character or competence, or who engage in fraud or deception in their practice of medicine.
3. Physicians shall respect the law, and also have an obligation to seek changes in any requirement believed to be contrary to their patients' best interests.
4. Physicians shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of law.
5. Physicians shall continue to study, apply, and advance scientific knowledge, make relevant information available to the public.
6. Physicians should seek consultation upon request, in doubtful or difficult cases; or whenever it appears that the quality of medical service may be enhanced thereby.
7. Physicians, except in emergencies, shall be free to choose whom to serve, with whom to associate, and the environment in which to provide services consistent with appropriate patient care.
8. Physicians should neither pay nor receive a commission for the referral of patients. Fees should be commensurate with the services rendered and the patient's ability to pay.
9. The honored ideals of the medical profession imply that the responsibilities of physicians extend first to the individual patient, but also to society where these responsibilities deserve their interest and participation in activities which have the purpose of maintaining or improving either the health or the well-being of the individual or the community.

6) **CSMS House of Delegates Handbook:** VOTED that the Handbook for each meeting of the House be in the hands of the respective county delegates and alternates no less than fourteen (14) days prior to each meeting of the House. Preparatory activities and meetings should be so structured to attain this goal.

7) **Amendments to Bylaws RE: Quorum, CSMS House of Delegates**—The House of Delegates adopted one amendment to the Bylaws (Article V—House of Delegates, Section 11—Quorum) the purpose of which is to enable the House of Delegates to begin its meetings with a majority of the sum of the number of delegates eligible to vote in the House.

8) **Proposed Amendments to the Bylaws** The Council submitted several Bylaw amendments which provide for Medical Student and Postgraduate Physician Membership in the Connecticut State Medical Society. These amendments were placed on the table for action at the next meeting of the House of Delegates and will be published in *Connecticut Medicine* at least once prior to that meeting.

Miscellaneous

a) **Report of Auxiliary to CSMS:** Mrs. Joseph Czarsty, President of the Auxiliary to CSMS, was commended for her speech to the House of Delegates, and it was VOTED to receive it for information and to refer her recommendations to the Council for consideration.

b) **Award to Connecticut Medicine:** On behalf of *Connecticut Medicine,* Editor J. Alfred Fabro, M.D., accepted the Medical Journalism Award from the Sandoz Pharmaceutical Association for Scientific Merit.

1980 ANNUAL MEETING HIGHLIGHTS

W. Raymond James, M.D., of Essex, right, the 143rd President of the Connecticut State Medical Society, accepts the President's gavel plaque symbolic of that office, from Edward A. Kamens, M.D., of Fairfield, left, retiring President.

Edward A. Kamens, M.D., of Fairfield, right, Past President, receives a gift of a camera, from Andrew J. Canzonetti, M.D., of Waterbury, left, Chairman of the Council of the CSMS.

AMA-ERF funds were awarded to Connecticut's two medical schools during ceremonies of the Annual Meeting. Pictured left to right are: Mrs. Michael Nezhad, of Waterbury, Chairperson of the AMA-ERF Auxiliary; Robert U. Massey, M.D., Dean of the University of Connecticut Medical School; Howard Levitin, M.D., Associate Dean, Yale University School of Medicine; and Edward A. Kamens, M.D., CSMS President. Yale University received $3,727.12, while UCONN received $825.

J. Alfred Fabro, M.D., of Torrington, right, Editor of *Connecticut Medicine,* accepts on behalf of that publication a medical journalism award for excellence in design and editorial content, from Ronald Norko, left, Regional Manager of Sandoz Pharmaceuticals.

Address of the President

EDWARD A. KAMENS

Mr. Speaker, Mr. Vice-Speaker, Members of the House, Honored Guests: I should like to thank all of my colleagues for the honor accorded me by having been given the privilege of serving as President of the Connecticut State Medical Society this past year.

This has been a most challenging experience and any success would have been nigh impossible without the efforts of the entire executive staff and of physicians, too numerous to mention, whose dedication to responsibility made possible those achievements that we may have attained during my term.

Serving as president of this organization is one of the most satisfying personal feelings one can have, while at the same time it is one of the most frustrating periods of one's adult life.

The president soon learns that despite intense efforts and unbounding enthusiasm, one cannot accomplish miracles. Successes are hard won and measured in minute quantities.

If there are legislative victories and if there is some organizational progress, it must, in all fairness, be credited to the cohesive functioning of the organization as a whole, rather than to the impact of one individual.

Having been given a platform from which to speak, I did avail myself this past year of every opportunity to proclaim my firm conviction that this profession, in overwhelming numbers is composed of dedicated, decent, devoted professionals with a deep-rooted concern for the welfare of their patients. It is a promise I made that I would repeat this many times, and it is a promise I have kept with all the intensity that I could muster. I also firmly believe that our long-standing dedication to the service of our patients, our commitment to self-discipline and to our continuing education have earned for us the right to admiration and the right to credibility for our efforts. That credibility is more vital to us know than ever before, for without it we shall not be able to obtain a fair hearing on issues that will affect the finest health system in the world.

I challenge anyone, anywhere, to dispute the fact that despite its flaws, this system delivers more care, is more innovative, is more productive, is more effective and maintains higher standards than any system in the world. It will continue to flourish and progress only if it is permitted to breathe freely instead of being choked by restrictive legislation.

In the past few years, however, our breath has been wheezened by a serious disorder which has afflicted all of us called asthmatic legislation.

It is legislation presumably dedicated to the consumer while simultaneously and insidiously victimizing him.

It is legislation perverted by a technocracy that produces volumes of paper about a numerology based on insufficient data with as much validity as most people are willing to attribute to numerology. In fact, it could give numerology a bad name.

It is legislation which places a premium on consumer majorities but excludes the ultimate consumers from these majorities because in the opinion of the technocrats they may not be sufficiently sophisticated to understand the complex issues of cost-benefit analysis that so-called "high level" planning entails. How presumptuous! Consumers make cost benefit decisions every day of their lives with every single purchase of goods or services that they make.

It is legislation which permits the exclusion of a new and innovative center for the mentally retarded in our state because, according to the reasoning of a planning agency, such a center, established by a multi-million dollar charitable gift, would average a higher than acceptable per diem cost; however, that same agency finds itself unable to place a per diem cost on the benefits that may ultimately accrue to the afflicted not only in our state but in our entire nation.

It is legislation which permits removal of patients from mental institutions to reduce costs but makes insufficient provisions for care in a new and unprotected external environment.

It is legislation which by restrictive covenants and regulations, presumably dedicated to cost-containment, removes incentive for construction of nursing homes in certain parts of our state, thereby causing a rise of 3 million additional dollars in Medicaid costs and generating 8.7 million additional dollars in hospital room and board costs as a result of such action.

It is legislation which permits subsidizing of a closed panel HMO with millions of dollars in unpaid loans while at the same time permitting it to go into bankruptcy proceedings without providing relief for it, and then places Blue Cross-Blue Shield in the position of attempting to salvage a bad investment by further pumping money into a marginal venture.

What is the upshot of all this? It's a depressing spectacle which will only succeed in discouraging innovation and decreasing individual productivity. We shall bear witness to the same untoward results in health care that we have already witnessed in areas of our government, our industry, and our defense establishment.

Because of adverse economic events we are now entering a period of governmental plateauing. And therefore some of you may feel that you can relax now because the depressed economy means less likelihood of federal expansionism. Some of you may feel that we are entering a period of well-deserved rest from intervention in our affairs. Some of you may even feel that a new *laissez-faire* philosophy should be permitted to take hold.

I choose to look upon this period somewhat differently. I choose to look upon this period not as a period of rest but as a period of opportunity. It will require not a lessening but an intensification of our personal effort and commitment.

We are the professionals and as the professionals we can recognize better than anyone else those problems that still exist for a public that expects and is entitled to the finest medical care in the world. But there are problems that simply will not go away without our efforts. We can and must address ourselves to the issues of accessibility of health care. We recognize that areas of diminished availability of care exist and we must cope with this. We face issues of distribution, cost containment and of problems created by a rapidly expanding technology and we must deal with these in imaginative, creative and daring ways. We know that demand for health care services can be insatiable and we know that our resources are not unlimited, but it is we who must become more deeply involved than ever before in helping the public make sound judgements about their own health care.

We are not only scientists, we are also humanists. Above all, we are more directly involved with those who will benefit from a flourishing health system than anyone else.

If by some stroke of legislative genius we were granted the power and the authority to have significant impact on the planning of this system, it should come as no surprise to anyone who has worked with the dedicated, imaginative, productive and intelligent physicians with whom I have been privileged to work for the past 20 years, that we could contribute significantly to the solution of some of the most vexing problems affecting the lives of our citizens.

We must therefore strive continually to obtain for ourselves the legislative authority to permit us to contribute to the welfare of our patients.

We physicians can no longer afford the luxury of just staying in our offices and simply practicing medicine.

And if we are not granted the legislative authority we seek, then we must participate as citizens and not just as doctors; and we must do so under whatever handicaps exist. No meeting of any agency can be too small or too boring to attend; no sacrifice in time can be too great and no effort to impact upon the system can be too unworthy. It is a time to be fully informed and to disseminate that information to others.

It is no longer a time for image building. It is a time for concrete action.

The time is long past for public service messages about colds and water safety. Now is the time for us to go public with facts and deeds that demonstrate that we really do give a damn about the health of our patients and the health of our profession.

In Memoriam

BLINKOFF, JACK J., University of Bern, Switzerland 1937. Dr. Blinkoff was a cardiologist in the Torrington area since 1946. He served in the U.S. Army during World War II and was awarded 5 battle stars, among them the Silver Star and Bronze Star medals. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Blinkoff died December 2, 1979, at the age of 66.

CAREY, WILLIAM C., Columbia University, 1933. Dr. Carey was a general practitioner in the New Haven area since 1935. During World War II he served in the U.S. Medical Corps and was twice awarded the Bronze Medal for gallantry in action. Before his retirement in 1977, he served on the Meriden Hospital medical board, first as secretary, and later as chief of staff. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Carey died April 1, 1980, at the age of 72.

EAGAN, E. CECIL, Albany Medical College, 1943. Dr. Eagan was a general practitioner in the Hartford area since 1947, specializing in Physical Medicine and Rehabilitation. He was the director of the Department of Physical Medicine at St. Francis Hospital and Medical Center. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Eagan died February 21, 1980, at the age of 64.

EHRLICH, EUGENE L., Bern Medical School, 1958. Dr. Ehrlich joined the staff of Newington Children's Hospital in 1965 and was director of its child life and psychiatry programs before being named clinical director of research psychiatry last year. He was an Army Air Corps veteran of World War II and an assistant clinical professor in psychiatry at the University of Connecticut School of Medicine. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Ehrlich died April 18, 1980, at the age of 64.

FARRELL, HENRY F., New York Medical College, 1954. Dr. Farrell was an orthopedic surgeon in the Litchfield area since 1956, and was chief of orthopedic surgery at the Charlotte Hungerford Hospital. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Farrell died January 28, 1980, at the age of 51.

FREEMAN, JOHN J., Temple University Medical School, 1933. Dr. Freeman was a general practitioner in the Windham area since 1937. He had a general practice of medicine in Newington for 20 years until joining the medical faculty at UConn in 1958. He retired eight years ago. Dr. Freeman died February 16, 1980, at the age of 77.

GOLDMAN, GEORGE, Yale University School of Medicine, 1910. Dr. Goldman was a general practitioner in the New Haven area since 1910 until 1930, then specialized in radiology until his retirement in 1967. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Goldman died January 20, 1980, at the age of 92.

HILL, PAUL R., Marquette Medical School, 1950. Dr. Hill was a general practitioner in the Fairfield area since 1952. He was on the staff of St. Vincent's Medical Center, Dinan Memorial Center, Golden Heights Manor and Lord Chamberlain Geriatric Home, and was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Hill died December 24, 1979, at the age of 59.

KERTESZ, JOHANN, University of Vienna, 1924. Dr. Kertesz was a general practitioner, specializing in industrial medicine, in the New Haven area since 1944. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Kertesz died February 11, 1980, at the age of 80.

SHEEHAN, GEORGE D., University College of Dublin, 1965. Dr. Sheehan was a medical oncologist in the Hartford area since 1966. He was on the medical staff of St. Francis Hospital Medical Center and Mercyknoll Infirmary in West Hartford, and was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Sheehan died January 7, 1980, at the age of 42.

NOT TO CIRCULATE